



Contaminant Candidate List Preliminary Regulatory Determination Support Document for Naphthalene

This page intentionally left blank.

Disclaimers

This document is designed to provide supporting information regarding the preliminary regulatory determination for naphthalene as part of the Contaminant Candidate List (CCL) evaluation process. This document is not a regulation, and it does not substitute for the Safe Drinking Water Act (SDWA) or the Environmental Protection Agency's (EPA's) regulations. Thus, it cannot impose legally-binding requirements on EPA, States, or the regulated community, and may not apply to a particular situation based upon the circumstances. Mention of trade names or commercial products does not constitute endorsement or recommendation for use.

This page intentionally left blank.

Acknowledgments

This document was prepared in support of the EPA's Office of Ground Water and Drinking Water preliminary regulatory determination for naphthalene as part of the Contaminant Candidate List (CCL) evaluation process. Dan Olson and Karen Wirth served as EPA's team leaders for the CCL regulatory determination process and James Taft as Standards and Risk Management Division Chief. Tara Cameron and Karen Wirth served as Work Assignment Managers. The CCL Work Group provided technical guidance throughout. In particular, Karen Wirth, Dan Olson, and Joyce Donohue provided scientific and editorial guidance. External expert reviewers and many stakeholders provided valuable advice to improve the CCL Program and this document. The Cadmus Group, Inc., served as the primary contractor providing support for this work. The major contributions of Matt Collins, Emily Brott, and Ashton Koo are gratefully acknowledged. George Hallberg served as Cadmus' Project Manager.

This page intentionally left blank.

USEPA, Office of Water Report: EPA 815-R-01-008, November, 2001

**CONTAMINANT CANDIDATE LIST
PRELIMINARY REGULATORY DETERMINATION
SUPPORT DOCUMENT FOR NAPHTHALENE**

Executive Summary

Naphthalene is a 1998 Contaminant Candidate List (CCL) regulatory determination priority contaminant. Naphthalene is one of the contaminants considered by the U.S. Environmental Protection Agency (EPA) for a regulatory determination. The available data on occurrence, exposure, and other risk considerations suggest that regulating naphthalene may not present a meaningful opportunity to reduce health risk. EPA presents preliminary CCL regulatory determinations and further analysis in the *Federal Register* Notice.

To make this preliminary regulatory determination for naphthalene, EPA used approaches guided by the National Drinking Water Advisory Council's (NDWAC) Work Group on CCL and Six-Year Review. The Safe Drinking Water Act (SDWA) requirements for National Primary Drinking Water Regulation (NPDWR) promulgation guided protocol development. The SDWA Section 1412(b)(1)(A) specifies that the determination to regulate a contaminant must be based on a finding that each of the following criteria are met: (i) "the contaminant may have adverse effects on the health of persons"; (ii) "the contaminant is known to occur or there is substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern"; and (iii) "in the sole judgement of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems." Available data were evaluated to address each of the three statutory criteria.

Naphthalene is a volatile organic compound (VOC) that is naturally present in fossil fuels such as petroleum and coal, and is produced when wood or tobacco are burned. Naphthalene is primarily used as an intermediary in the production of phthalate plasticizers, resins, phthaleins, dyes, pharmaceuticals, and insect repellents. Crystalline naphthalene is used as a moth repellent and a solid block deodorizer for diaper pails and toilets. Naphthalene is also used to make the insecticide carbaryl and synthetic leather tanning agents. Releases of naphthalene to the environment, reported through the Toxic Release Inventory (TRI), are widespread. The occurrence of naphthalene in site samples recorded in the Agency for Toxic Substances and Disease Registry's (ATSDR) Hazardous Substance Release and Health Effects Database (HazDat) and at National Priorities List (NPL) hazardous waste sites provides further evidence for the widespread use and environmental release of naphthalene.

Naphthalene was monitored from 1987 to 1999 under the SDWA Unregulated Contaminant Monitoring (UCM) program. Naphthalene is also monitored or regulated by other federal programs including the Clean Water Act Priority Pollutants list, the Clean Air Act Hazardous Air Pollutant list, the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), the Resource Conservation and Recovery Act (RCRA), the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), and the Toxic Release Inventory (TRI).

Because of concerns about human health risk, EPA issued a drinking water health advisory for naphthalene in 1990 at 100 µg/L and later recommended guidelines for exposure to naphthalene in drinking water. Other federal agencies and organizations have issued recommendations for occupational exposure.

Naphthalene has been detected in ambient ground water as noted by the United States Geological Survey's (USGS) National Water Quality Assessment (NAWQA) program. Detection frequencies and concentrations in ground water are relatively low, with naphthalene occurrence considerably higher in urban wells than in rural wells. Naphthalene detection frequencies in urban and highway surface runoff are slightly higher than in ground water, but concentrations are lower. Maximum concentrations in surface runoff and in ground water, however, are both well below the Health Reference Level (HRL) of 140 µg/L, a preliminary health effect level used for this analysis.

Naphthalene has also been detected in PWS samples collected under SDWA. Occurrence estimates are low, with less than 0.5% of all samples showing detections for both rounds of UCM monitoring. The percentages of public water systems (PWSs) with detections are 0.75% and 1.18% for the two rounds of UCM monitoring. Percentages of PWSs with detections greater than half the Health Reference Level ($> \frac{1}{2}$ HRL) are considerably lower: approximately 0.01% for both rounds. National estimates for the population served by PWSs with detections are also low, especially for detections greater than the HRL. It is estimated, based upon Round 1 data, that less than 0.01% of the national PWS population is served by systems with detections greater than the HRL (approximately 16,000 people). While detection frequencies and concentrations are low, the geographic distribution of detections is widespread. Thirty two out of the 43 States reporting UCM data for naphthalene report detections. Only 1 State reports detections greater than the HRL.

The available toxicological data indicate that naphthalene has the potential to cause adverse health effects in humans and animals at high doses. In humans, hemolytic anemia is the most common manifestation of naphthalene toxicity. There are inadequate data to support a conclusion about the carcinogenicity of naphthalene by the oral route of exposure.

Monitoring data indicate that naphthalene is infrequently detected in public water supplies. Furthermore, when naphthalene is detected, it very rarely exceeds the HRL or a value of one-half of the HRL. Additionally, when average daily intakes from drinking water are compared with intakes from food, air, and soil, drinking water accounts for a relatively small proportion of total naphthalene intake. Therefore, regulation of naphthalene in drinking water is unlikely to represent a meaningful opportunity for health risk reduction.

Table of Contents

Disclaimers	i
Acknowledgments	iii
Executive Summary	v
Table of Contents	vii
List of Tables	ix
List of Figures	xi
1.0 INTRODUCTION	1
1.1 Purpose and Scope	1
1.2 Statutory Framework/Background	1
1.3 Statutory History of Naphthalene	2
1.4 Regulatory Determination Process	3
1.5 Determination Outcome	4
2.0 CONTAMINANT DEFINITION	4
2.1 Physical and Chemical Properties	4
2.2 Environmental Fate/Behavior	5
3.0 OCCURRENCE AND EXPOSURE	5
3.1 Use and Environmental Release	6
3.1.1 Production and Use	6
3.1.2 Environmental Release	6
3.2 Ambient Occurrence	7
3.2.1 Data Sources and Methods	8
3.2.2 Results	8
3.3 Drinking Water Occurrence	9
3.3.1 Data Sources, Data Quality, and Analytical Approaches	10
3.3.1.1 UCM Rounds 1 and 2	10
3.3.1.2 Developing a Nationally Representative Perspective	11
3.3.1.2.1 Cross-Section Development	11
3.3.1.2.2 Cross-Section Evaluation	12
3.3.1.3 Data Management and Analysis	13
3.3.1.4 Occurrence Analysis	14
3.3.2 Results	16
3.3.2.1 Occurrence Estimates	16
3.3.2.2 Regional Patterns	18
3.4 Conclusion	22
4.0 HEALTH EFFECTS	22
4.1 Hazard Characterization and Mode of Action Implications	22
4.2 Dose-Response Characterization and Implications in Risk Assessment	23
4.3 Relative Source Contribution	25
4.4 Sensitive Populations	25
4.5 Exposure and Risk Information	26

4.6 Conclusion	26
5.0 TECHNOLOGY ASSESSMENT	26
5.1 Analytical Methods	26
5.2 Treatment Technology	27
6.0 SUMMARY AND CONCLUSIONS - DETERMINATION OUTCOME	27
References	29
Appendix A: Abbreviations and Acronyms	33

List of Tables

Table 2-1: Physical and chemical properties	5
Table 3-1: Environmental releases (in pounds) for naphthalene in the United States (1988-1998)	7
Table 3-2: Naphthalene detections and concentrations in ground water	9
Table 3-3: Cross-section States for Round 1 (24 States) and Round 2 (20 States)	13
Table 3-4: Summary occurrence statistics for naphthalene	17

This page intentionally left blank.

List of Figures

Figure 3-1: Geographic distribution of cross-section States for Round 1 (left) and Round 2 (right) . . .	13
Figure 3-2: States with PWSs with detections of naphthalene for all States with data in URCIS (Round 1) and SDWIS/FED (Round 2)	19
Figure 3-3: States with PWSs with detections of naphthalene (any PWSs with results greater than the Minimum Reporting Level [MRL]) for Round 1 (above) and Round 2 (below) cross-section States	20
Figure 3-4: Cross-section States (Round 1 and Round 2 combined) with PWSs with detections of naphthalene (above) and concentrations greater than the Health Reference Level (below)	21

This page intentionally left blank.

1.0 INTRODUCTION

1.1 Purpose and Scope

This document presents scientific data and summaries of technical information prepared for, and used in, the Environmental Protection Agency's (EPA) regulatory determination for naphthalene. Information regarding naphthalene's physical and chemical properties, environmental fate, occurrence and exposure, and health effects is included. Analytical methods and treatment technologies are also discussed. Furthermore, the regulatory determination process is described to provide the rationale for the decision.

1.2 Statutory Framework/Background

The Safe Drinking Water Act (SDWA), as amended in 1996, requires the United States Environmental Protection Agency (EPA) to publish a list of contaminants (referred to as the Contaminant Candidate List, or CCL) to assist in priority-setting efforts. The contaminants included on the CCL were not subject to any current or proposed National Primary Drinking Water Regulations (NPDWR), were known or anticipated to occur in public water systems, and were known or suspected to adversely affect public health. These contaminants therefore may require regulation under SDWA. The first Drinking Water CCL was published on March 2, 1998 (USEPA, 1998b; 63 FR 10273), and a new CCL must be published every five years thereafter.

The 1998 CCL contains 60 contaminants, including 50 chemicals or chemical groups, and 10 microbiological contaminants or microbial groups. The SDWA also requires the Agency to select 5 or more contaminants from the current CCL and determine whether or not to regulate these contaminants with an NPDWR. Regulatory determinations for at least 5 contaminants must be completed 3½ years after each new CCL.

Language in SDWA Section 1412(b)(1)(A) specifies that the determination to regulate a contaminant must be based on a finding that each of the following criteria are met:

Statutory Finding i: ...the contaminant may have adverse effects on the health of persons;

Statutory Finding ii: the contaminant is known to occur or there is substantial likelihood that the contaminant will occur in public water systems with a frequency and at levels of public health concern; and

Statutory Finding iii: in the sole judgement of the Administrator, regulation of such contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems.

The geographic distribution of the contaminant is another factor evaluated to determine whether it occurs at the national, regional, or local level. This consideration is important because the Agency is charged with developing national regulations and it may not be appropriate to develop NPDWRs for regional or local contamination problems.

EPA must determine if regulating this CCL contaminant will present a meaningful opportunity to reduce health risk based on contaminant occurrence, exposure, and other risk considerations. The Office of Ground Water and Drinking Water (OGWDW) is charged with gathering and analyzing the occurrence, exposure, and risk information necessary to support this regulatory decision. The OGWDW must evaluate when and where this contaminant occurs, and what would be the exposure and risk to

public health. EPA must evaluate the impact of potential regulations as well as determine the appropriate measure(s) for protecting public health.

For each of the regulatory determinations, EPA must first publish in the *Federal Register* the draft determinations for public comment. EPA will respond to the public comments received, and will then finalize regulatory determinations. If the Agency finds that regulations are warranted, the regulations must then be formally proposed within 24 months, and promulgated eighteen months later. EPA has determined that there is sufficient information to support a regulatory determination for naphthalene.

1.3 Statutory History of Naphthalene

Naphthalene has been monitored under the SDWA Unregulated Contaminant Monitoring (UCM) program since 1987. It was among 14 volatile organic compounds (VOCs) included for discretionary monitoring (USEPA, 1987; 52 FR 25690). Monitoring for naphthalene under UCM continued throughout the 1990s, but ceased for small public water systems (PWSs) under a direct final rule published January 8, 1999 (USEPA, 1999a; 64 FR 1494). Monitoring ended for large PWSs with promulgation of the new Unregulated Contaminant Monitoring Regulation (UCMR) issued September 17, 1999 (USEPA, 1999b; 64 FR 50556) and effective January 1, 2001. At the time the UCMR lists were developed, the Agency concluded there were adequate monitoring data for a regulatory determination. This obviated the need for continuing monitoring under the new UCMR list.

EPA issued a drinking water health advisory for naphthalene in 1990, and later recommended guidelines for exposure to naphthalene in drinking water (USEPA, 1990; ATSDR, 1996). As part of the CCL process, health effects data have been reviewed. These are summarized in section 4.0 of this document.

Naphthalene is regulated or monitored by other federal programs as well. It is included on the Clean Water Act Priority Pollutants list for which the EPA establishes ambient water quality criteria. It is also listed as a Hazardous Air Pollutant under the Clean Air Act and subject to Best Available Control Technology limits. Both the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or "Superfund") and the Resource Conservation and Recovery Act (RCRA) include it as a hazardous substance and a hazardous constituent, respectively (USEPA, 2000a). CERCLA's listing requires reporting of releases over a certain "reportable quantity" which, for naphthalene, is 100 pounds (ATSDR, 1996).

Naphthalene's sale, use, and distribution is controlled under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). FIFRA was most recently amended in 1996 under the Food Quality Protection Act (FQPA). FIFRA requires registration of all pesticides with EPA, and certain labeling, application, and use restrictions. Moreover, pesticide manufacturing plants must be registered, and the manufacturer must provide EPA with scientific data regarding the product's efficacy and demonstrating that it does not pose an unreasonable risk to people or the environment (USEPA, 1998a; USEPA, 2000a). Naphthalene is also a Toxic Release Inventory (TRI) chemical. The TRI was established by the Emergency Planning and Community Right-to-Know Act (EPCRA). EPCRA requires certain industrial sectors to publicly report the environmental release or transfer of chemicals included in this inventory (USEPA, 1996a).

Finally, the Occupational Safety and Health Administration (OSHA) recommends an occupational exposure limit of 10 parts naphthalene per million in air (10 ppm) for an 8-hour workday over a 40-hour workweek. The American Conference of Governmental and Industrial Hygienists (ACGIH) and the Mine Safety and Health Administration (MSHA) recommend the same weekly limit (USDHHS, 1993). The National Institute for Occupational Safety and Health (NIOSH) considers over 250 ppm of naphthalene in air to be life-threatening (ATSDR, 1996).

1.4 Regulatory Determination Process

In developing a process for the regulatory determinations, EPA sought input from experts and stakeholders. EPA asked the National Research Council (NRC) for assistance in developing a scientifically sound approach for deciding whether or not to regulate contaminants on the current and future CCLs. The NRC's Committee on Drinking Water Contaminants recommended that EPA: (1) gather and analyze health effects, exposure, treatment, and analytical methods data for each contaminant; (2) conduct a preliminary risk assessment for each contaminant based on the available data; and (3) issue a decision document for each contaminant describing the outcome of the preliminary risk assessment. The NRC noted that in using this decision framework, EPA should keep in mind the importance of involving all interested parties.

One of the formal means by which EPA works with its stakeholders is through the National Drinking Water Advisory Council (NDWAC). The NDWAC comprises members of the general public, State and local agencies, and private groups concerned with safe drinking water, and advises the EPA Administrator on key aspects of the Agency's drinking water program. The NDWAC provided specific recommendations to EPA on a protocol to assist the Agency in making regulatory determinations for current and future CCL contaminants. Separate but similar protocols were developed for chemical and microbial contaminants. These protocols are intended to provide a consistent approach to evaluating contaminants for regulatory determination, and to be a tool that will organize information in a manner that will communicate the rationale for each determination to stakeholders. The possible outcomes of the regulatory determination process are: a decision to regulate, a decision not to regulate, or a decision that some other action is needed (e.g., issuance of guidance).

The NDWAC protocol uses the three statutory requirements of SDWA Section 1412(b)(1)(A)(i)-(iii) (specified in section 1.2) as the foundation for guiding EPA in making regulatory determination decisions. For each statutory requirement, evaluation criteria were developed and are summarized below.

To address whether a contaminant may have adverse effects on the health of persons (statutory requirement (i)), the NDWAC recommended that EPA characterize the health risk and estimate a health reference level for evaluating the occurrence data for each contaminant.

Regarding whether a contaminant is known to occur, or whether there is substantial likelihood that the contaminant will occur, in public water systems with a frequency, and at levels, of public health concern (statutory requirement (ii)), the NDWAC recommended that EPA consider: (1) the actual and estimated national percent of public water systems (PWSs) reporting detections above half the health reference level; (2) the actual and estimated national percent of PWSs with detections above the health reference level; and (3) the geographic distribution of the contaminant.

To address whether regulation of a contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems (statutory requirement (iii)) the NDWAC recommended that EPA consider estimating the national population exposed above half the health reference level and the national population exposed above the health reference level.

The approach EPA used to make preliminary regulatory determinations followed the general format recommended by the NRC and the NDWAC to satisfy the three SDWA requirements under section 1412(b)(1)(A)(i)-(iii). The process was independent of many of the more detailed and comprehensive risk management factors that will influence the ultimate regulatory decision making process. Thus, a decision to regulate is the beginning of the Agency regulatory development process, not the end.

Specifically, EPA characterized the human health effects that may result from exposure to a contaminant found in drinking water. Based on this characterization, the Agency estimated a health reference level (HRL) for each contaminant.

For each contaminant EPA estimated the number of PWSs with detections $> \frac{1}{2}$ HRL and $>$ HRL, the population served at these benchmark values, and the geographic distribution, using a large number of occurrence data (approximately seven million analytical points) that broadly reflect national coverage. Round 1 and Round 2 UCM data, evaluated for quality, completeness, bias, and representativeness, were the primary data used to develop national occurrence estimates. Use and environmental release information, additional drinking water data sets (e.g., State drinking water data sets, EPA National Pesticide Survey, and Environmental Working Group data reviews), and ambient water quality data (e.g., NAWQA, State and regional studies, and the EPA Pesticides in Ground Water Database) were also consulted.

The findings from these evaluations were used to determine if there was adequate information to evaluate the three SDWA statutory requirements and to make a preliminary determination of whether to regulate a contaminant.

1.5 Determination Outcome

The Agency has made a preliminary determination not to regulate naphthalene with an NPDWR because it is not known to occur in public water systems at levels of public health concern. Monitoring data indicate that naphthalene is infrequently detected in public water supplies. When naphthalene is detected, it very rarely exceeds the Health Reference Level (HRL) or a value of one-half of the HRL. All preliminary CCL regulatory determinations will be presented in the *Federal Register* Notice. The following sections summarize the data used by the Agency to reach this preliminary decision.

2.0 CONTAMINANT DEFINITION

Naphthalene, a volatile organic compound (VOC), is a white solid with a strong odor. Common synonyms for naphthalene include: mothballs, mothflakes, tar camphor, white tar, naphthene, and albocarbon. Naphthalene is naturally present in fossil fuels such as petroleum and coal, and is produced when wood or tobacco are burned. Most of naphthalene consumption (60%) is as an intermediary in the production of phthalate plasticizers, resins, phthaleins, dyes, pharmaceuticals, and insect repellents. Crystalline naphthalene is used as a moth repellent and a solid block deodorizer for diaper pails and toilets. Naphthalene is also used to make the insecticide carbaryl, synthetic leather tanning agents, and surface active agents (ATSDR, 1995).

2.1 Physical and Chemical Properties

Table 2-1 lists summary information regarding naphthalene's physical and chemical properties. Also included are its CAS Registry Number and molecular formula.

Table 2-1: Physical and chemical properties

Identification	
CAS number	91-20-3
Molecular Formula	C ₁₀ H ₈
Physical and Chemical Properties	
Boiling Point	218 °C at 760 mm Hg
Melting Point	80.5 °C
Molecular Weight	128.19 g/mol
Log K _{oc}	2.97
Log K _{ow}	3.29
Water Solubility	31.7 mg/L at 25 °C
Vapor Pressure	0.087 mm Hg at 25 °C
Henry's Law Constant [†]	1.88 x 10 ⁻²

source: ATSDR, 1995.

[†] note: this quantity is expressed in a dimensionless form.

2.2 Environmental Fate/Behavior

Naphthalene solid evaporates easily in air and is readily degraded in the atmosphere by hydroxyl radicals (half life < 1 day). The half life of naphthalene in water depends on local conditions and varies from a couple of days to a few months. Biodegradation of naphthalene in soil occurs quickly (half life a few hours to days) if the soil is contaminated with other polycyclic aromatic hydrocarbons. If the soil is free of such contaminants, the half life of naphthalene is greater than 80 days (Howard, 1989).

Naphthalene's evaporation rate is significant at the soil surface but slowly decreases as depth increases. Its sorption to soil is slow to moderate depending on the soil's organic carbon content. Naphthalene travels rapidly through sandy soil (Howard, 1989).

When released into the water, naphthalene either volatilizes, degrades by photolysis, adsorbs to surfaces, or biodegrades. It biodegrades significantly faster when adsorbed to sediment than when contained in the upper layers of water. Volatilization is primarily responsible for naphthalene's removal in turbulent water. In slower moving waters, biodegradation is the more significant process. Naphthalene can also biodegrade in ground water under aerobic conditions (Howard, 1989).

3.0 OCCURRENCE AND EXPOSURE

This section examines the occurrence of naphthalene in drinking water. While no complete national database exists of unregulated or regulated contaminants in drinking water from public water systems

(PWSs) collected under SDWA, this report aggregates and analyzes existing State data that have been screened for quality, completeness, and representativeness. Populations served by PWSs exposed to naphthalene are estimated, and the occurrence data are examined for regional or other special trends. To augment the incomplete national drinking water data and aid in the evaluation of occurrence, information on the use and environmental release, as well as ambient occurrence of naphthalene, is also reviewed.

3.1 Use and Environmental Release

3.1.1 Production and Use

Naphthalene is naturally present in fossil fuels such as petroleum and coal, and is generated when wood or tobacco are burned. Naphthalene is produced in commercial quantities from either coal tar or petroleum. Most of the naphthalene produced in the United States comes from petroleum by the dealkylation of methyl naphthalenes in the presence of hydrogen at high temperature and pressure. Another common production method is the distillation and fractionation of coal tar. Most naphthalene consumption (60%) is through use as an intermediary in the production of phthalate plasticizers, resins, phthalic acids, dyes, pharmaceuticals, and insect repellents. Crystalline naphthalene is used as a moth repellent and a solid block deodorizer for diaper pails and toilets. Naphthalene is also used to make the insecticide carbaryl, synthetic leather tanning agents, and surface active agents (ATSDR, 1995).

Naphthalene production in the United States dropped from 900 million lbs/yr in 1968 to 354 million lbs/yr in 1982. Approximately 7 million lbs of naphthalene were imported and 9 million lbs were exported in 1978. By 1989, imports had dropped to 4 million lbs, and exports increased dramatically to 21 million lbs (ATSDR, 1995).

3.1.2 Environmental Release

Naphthalene is listed as a toxic release inventory chemical. In 1986, the Emergency Planning and Community Right-to-Know Act (EPCRA) established the Toxic Release Inventory (TRI) of hazardous chemicals. Created under the Superfund Amendments and Reauthorization Act (SARA) of 1986, EPCRA is also sometimes known as SARA Title III. The EPCRA mandates that larger facilities publicly report when TRI chemicals are released into the environment. This public reporting is required for facilities with more than 10 full-time employees that annually manufacture or produce more than 25,000 pounds, or use more than 10,000 pounds, of TRI chemical (USEPA, 1996a; USEPA, 2000e).

Under these conditions, facilities are required to report the pounds per year of naphthalene released into the environment both on- and off-site. The on-site quantity is subdivided into air emissions, surface water discharges, underground injections, and releases to land (see Table 3-1). For naphthalene, air emissions constitute most of the on-site releases. Also, surface water discharges exhibit no obvious trend over the period for which data is available (1988-1998), but discharges hit a low in 1996 and 1997, and increase again in 1998. These TRI data for naphthalene were reported from 47 States (excluding ID, NH, VT) indicating the widespread production or use of this chemical (USEPA, 2000c).

Table 3-1: Environmental releases (in pounds) for naphthalene in the United States (1988-1998)

Year	On-Site Releases				Off-Site Releases	Total On- & Off-site Releases
	Air Emissions	Surface Water Discharges	Underground Injection	Releases to Land		
1998	3,374,439	34,148	191,677	1,251,040	827,708	5,679,012
1997	2,449,488	13,333	187,927	82,204	491,124	3,224,076
1996	2,863,431	11,836	296,776	301,513	582,717	4,056,273
1995	2,690,669	43,311	44,318	32,085	474,106	3,284,489
1994	2,889,514	28,557	97,186	47,017	496,501	3,558,775
1993	2,744,887	31,179	79,814	49,886	334,985	3,240,751
1992	2,626,986	28,925	78,227	1,667,150	667,556	5,068,844
1991	2,927,511	31,508	39,112	55,278	983,371	4,036,780
1990	3,912,253	36,821	28,130	143,196	919,225	5,039,625
1989	3,523,562	146,983	39,552	118,409	1,054,602	4,883,108
1988	5,165,426	22,518	50,946	123,697	1,359,184	6,721,771

source: USEPA 2000c

Although the TRI data can be useful in giving a general idea of release trends, it is far from exhaustive and has significant limitations. For example, only industries which meet TRI criteria (at least 10 full-time employees and manufacture and processing of quantities exceeding 25,000 lbs/yr, or use of more than 10,000 lbs/yr) are required to report releases. These reporting criteria do not account for releases from smaller industries. Threshold manufacture and processing quantities also changed from 1988-1990 (dropping from 75,000 lbs/yr in 1988 to 50,000 lbs/yr in 1989 to its current 25,000 lbs/yr in 1990) creating possibly misleading data trends. Finally, the TRI data is meant to reflect releases and should not be used to estimate general exposure to a chemical (USEPA, 2000d; USEPA, 2000b).

Naphthalene is also included in the Agency for Toxic Substances and Disease Registry's (ATSDR) Hazardous Substance Release and Health Effects Database (HazDat). This database records detections of listed chemicals in site samples; naphthalene was detected in 44 States (States without detections are AK, AZ, HI, NV, ND, UT; ATSDR, 2000). The National Priorities List (NPL) of hazardous waste sites, created in 1980 by CERCLA, is a listing of some of the most health-threatening waste sites in the United States. Naphthalene was again detected in all but six States (excluding HI, NE, NV, NM, ND, WV; USEPA, 1999c).

In summary, most of naphthalene's consumption is through use as an intermediary in the production of phthalate plasticizers, resins, phthaleins, dyes, pharmaceuticals, and insect repellents. Its production in the United States declined from 1968 to 1982, however its import decreased and export increased from 1978 to 1989. The widespread use and production of naphthalene in the United States is evidenced by its presence in hazardous waste sites in at least 44 States (at NPL sites), its presence in site samples in at least 44 States (listed in ATSDR's HazDat), and its direct release into the environment in at least 47 States (based on TRI data).

3.2 Ambient Occurrence

To understand the presence of a chemical in the environment, an examination of ambient occurrence is useful. In a drinking water context, ambient water is source water existing in surface waters and aquifers before treatment. The most comprehensive and nationally consistent data describing ambient water quality in the United States are being produced through the United States Geological Survey's (USGS) National Water Quality Assessment (NAWQA) program. (NAWQA, however, is a relatively young program and complete national data are not yet available from their entire array of sites across the nation.)

3.2.1 Data Sources and Methods

To examine water quality status and trends in the United States, the USGS instituted the NAWQA program in 1991. NAWQA is designed and implemented in such a manner as to allow consistency and comparison between representative study basins located around the country, facilitating interpretation of natural and anthropogenic factors affecting water quality (Leahy and Thompson, 1994).

The NAWQA program consists of 59 significant watersheds and aquifers referred to as “study units.” The study units represent approximately two thirds of the overall water usage in the United States and a similar proportion of the population served by public water systems. Approximately one half of the nation’s land area is represented (Leahy and Thompson, 1994).

To facilitate management and make the program cost-effective, approximately one third of the study units at a time engage in intensive assessment for a period of 3 to 5 years. This is followed by a period of less intensive research and monitoring that lasts between 5 and 7 years. This way all 59 study units rotate through intensive assessment over a ten-year period (Leahy and Thompson, 1994). The first round of intensive monitoring (1991-96) targeted 20 watersheds. This first group was more heavily slanted toward agricultural basins. A national synthesis of results from these study units and other research initiatives focusing on pesticides and nutrients is being compiled and analyzed (Kolpin et al., 2000; Larson et al., 1999).

For VOCs, the national synthesis will compile data from the first and second rounds of intensive assessments. Study units assessed in the second round represent conditions in more urbanized basins, but initial results are not yet available. However, VOCs were analyzed in the first round of intensive monitoring and data are available for these study units (Squillace et al., 1999). The minimum reporting level (MRL) for most VOCs, including naphthalene, was 0.2 µg/L (Squillace et al., 1999).

Furthermore, the NAWQA program has compiled, by study unit, data collected from local, State, and other Federal agencies to augment its own data. The data set provides an assessment of VOCs in untreated ambient ground water of the coterminous United States for the period 1985-1995 (Squillace et al., 1999). Data were included in the compilation if they met certain criteria for collection, analysis, well network design, and well construction (Lapham et al., 1997). They represent both rural and urban areas, but should be viewed as a progress report as NAWQA data continue to be collected that may influence conclusions regarding occurrence and distribution of VOCs (Squillace et al., 1999).

The National Highway Runoff Data and Methodology Synthesis has reviewed 44 highway and urban runoff studies implemented since 1970 (Lopes and Dionne, 1998). Two national studies were included in this review: the National Urban Runoff Program (NURP) and studies associated with the EPA National Pollution Discharge Elimination System (NPDES) municipal stormwater permits. NURP, conducted in the 1970s and early 1980s, had the most extensive geographic distribution. The NPDES studies took place in the early to mid- 1990s (Lopes and Dionne, 1998). Naphthalene was an analyte in both studies.

3.2.2 Results

Naphthalene was detected in both rural and urban wells of the local, State, and federal data set compiled by NAWQA (Table 3-2). The data represent untreated ambient ground water of the conterminous United States for the years 1985-1995 (Squillace et al., 1999). Detection frequencies and median concentrations are low, especially for rural areas. Occurrence of naphthalene in rural areas is an order of magnitude lower than in urban areas, a trend generally observed for VOCs throughout the United States (Miller, 2000). The exception to this trend for naphthalene is the maximum concentration, a

parameter more likely to be influenced by extreme values (outliers) that do not well represent the overall data.

Table 3-2: Naphthalene detections and concentrations in ground water

Detection frequency (% of sampled wells > MRL*)		Concentrations (of detections; µg/L)		Percent exceeding HAL** (20 µg/L)	
		<u>median</u>	<u>maximum</u>	all wells	drinking water wells
<i>urban</i>	3.0%	3.9	43	0.4	0
<i>rural</i>	0.2%	0.4	70	0.1	0

after Squillace et al., 1999

* MRL for naphthalene in water: 0.2 µg/L

** USEPA, 1996b; ATSDR, 1996

The NURP and NPDES studies analyzing urban and highway runoff also found naphthalene (Lopes and Dionne, 1998). Naphthalene was detected in 11% of NURP samples making it among the 3 most detected VOCs in the study. Its detection frequency was 7% in the NPDES studies. The maximum concentration was 2.3 µg/L in NURP samples and 5.1 µg/L in NPDES samples.

The maximum values for urban and highway runoff are well below the Health Advisory Level (HAL) of 20 µg/L cited by Lopes and Dionne (1998), the HAL in effect at the time (USEPA, 1996b). The ground water studies also reported few exceedances of the 20 µg/L HAL (Squillace et al., 1999). The maximum values for runoff and ground water are considerably less than the current HAL of 100 µg/L (USEPA, 2000f) and even more so for the Health Reference Level (HRL) of 140 µg/L used as a preliminary health effects level for the drinking water data analysis presented below.

3.3 Drinking Water Occurrence

The SDWA, as amended in 1986, required PWSs to monitor for specified “unregulated” contaminants, on a five year cycle, and to report the monitoring results to the States. Unregulated contaminants do not have an established or proposed NPDWR, but they are contaminants that were formally listed and required for monitoring under federal regulations. The intent was to gather scientific information on the occurrence of these contaminants to enable a decision as to whether or not regulations were needed. All non-purchased community water systems (CWSs) and non-purchased non-transient non-community water systems (NTNCWSs), with greater than 150 service connections, were required to conduct this unregulated contaminant monitoring. Smaller systems were not required to conduct this monitoring under federal regulations, but were required to be available to monitor if the State decided such monitoring was necessary. Many States collected data from smaller systems. Additional contaminants were added to the UCM program in 1991 (USEPA, 1991; 56 FR 3526) for required monitoring that began in 1993 (USEPA, 1992; 57 FR 31776).

Naphthalene has been monitored under the SDWA UCM program since 1987 (USEPA, 1987; 52 FR 25690). Monitoring for naphthalene under UCM continued throughout the 1990s, but ceased for small PWSs under a direct final rule published January 8, 1999 (USEPA, 1999a; 64 FR 1494). Monitoring ended for large PWSs with promulgation of the new Unregulated Contaminant Monitoring Regulation (UCMR) issued September 17, 1999 (USEPA, 1999b; 64 FR 50556) and effective January 1, 2001. At

the time the UCMR lists were developed, the Agency concluded there were adequate monitoring data for a regulatory determination. This obviated the need for continued monitoring under the new UCMR list.

3.3.1 Data Sources, Data Quality, and Analytical Approaches

Currently, there is no complete national record of unregulated or regulated contaminants in drinking water from public water systems collected under SDWA. Many States have submitted their unregulated contaminant PWS monitoring data to EPA databases, but there are issues of data quality, completeness, and representativeness. Nonetheless, a significant amount of State data are available for UCM contaminants that can provide estimates of national occurrence. The contaminant occurrence analyses findings presented in this report are based on a national cross-section of aggregated state data (i.e., a representative subset of available state data) derived from the Safe Drinking Water Information System (Federal version; SDWIS/FED) database.

The National Contaminant Occurrence Database (NCOD) is an interface to the actual occurrence data stored in the SDWIS/FED and can be queried to provide a summary of the data in SDWIS/FED for a particular contaminant. The data used in this report were derived from the data in SDWIS/FED and another database called the Unregulated Contaminant Information System (URCIS). Note, however, that the SDWIS/FED data used in this report have been reviewed, edited, and filtered to meet various data quality objectives for the purposes of this analysis. Hence, not all data from a particular source were used, only data meeting the quality objectives described below. The sources of these data, their quality and national aggregation, and the analytical methods used to estimate a given contaminant's national occurrence (from these data) are discussed in this section (for further details see USEPA, 2001a, 2001c).

3.3.1.1 UCM Rounds 1 and 2

The 1987 UCM contaminants include 34 VOCs, divided into two groups: one with 20 VOCs for mandatory monitoring, and the other with 14 VOCs for discretionary monitoring (USEPA, 1987; 52 FR 25690). Naphthalene was among the 14 VOCs included for discretionary monitoring. The UCM (1987) contaminants were first monitored coincident with the Phase I regulated contaminants, during the 1988-1992 period. This period is often referred to as "Round 1" monitoring. The monitoring data collected by the PWSs were reported to the States (as primacy agents), but there was no protocol in place to report these data to EPA. These data from Round 1 were collected by EPA from many States over time.

The Round 1 data were put into a database called the Unregulated Contaminant Information System, or URCIS. Most of the Phase 1 regulated contaminants were also VOCs. Both the unregulated and regulated VOCs are analyzed using the same sample and the same laboratory methods. Hence, the URCIS database includes data on all of these 62 contaminants: the 34 UCM (1987) VOCs; the 21 regulated Phase 1 VOCs; 2 regulated synthetic organic contaminants (SOCs); and 5 miscellaneous contaminants that were voluntarily reported by some States (e.g., isomers of other organic contaminants).

The 1993 UCM contaminants include 13 SOC and 1 inorganic contaminant (IOC) (USEPA, 1992; 57 FR 31776). Monitoring for the UCM (1993) contaminants began coincident with the Phase II/V regulated contaminants in 1993 through 1998. This is often referred to as "Round 2" monitoring. The UCM (1987) contaminants were also included in the Round 2 monitoring. As with other monitoring data, PWSs reported these results to the States. EPA, during the past several years, requested that the States submit these historic data to EPA.

The details of the actual individual monitoring periods are complex. The timing of required monitoring was staggered related to different size classes of PWSs, and the program was implemented somewhat differently by different States. While Round 1 includes the period from 1988-1992, it also

includes results from samples analyzed prior to 1988 that were “grandfathered” into the database (for further details see USEPA, 2001a, 2001c).

3.3.1.2 Developing a Nationally Representative Perspective

The Round 1 and Round 2 databases contain contaminant occurrence data from a total of 40 and 35 primacy entities (largely States), respectively. However, data from some States are incomplete and biased. Furthermore, the national representativeness of the data is problematic because the data were not collected in a systematic or random statistical framework. These State data could be heavily skewed to low-occurrence or high-occurrence settings. Hence, the State data were evaluated based on pollution-potential indicators and the spatial/hydrologic diversity of the nation. This evaluation enabled the construction of a cross-section from the available State data sets that provides a reasonable representation of national occurrence.

A national cross-section comprised of the Round 2 state contaminant occurrence databases was established using the approach developed for the EPA report *A Review of Contaminant Occurrence in Public Water Systems* (USEPA, 1999d). This approach was developed to support occurrence analyses for EPA’s Chemical Monitoring Reform (CMR) evaluation, and was supported by peer reviewers and stakeholders. The approach cannot provide a “statistically representative” sample because the original monitoring data were not collected or reported in an appropriate fashion. However, the resultant “national cross-section” of states should provide a clear indication of the central tendency of the national data. The remainder of this section provides a summary description of how the national cross-section from the SDWIS/FED (Round 2) database was developed. The details of the approach are presented in other documents (USEPA, 2001a, 2001b); readers are referred to these for more specific information.

3.3.1.2.1 Cross-Section Development

As a first step in developing the cross-section, the State data contained in the URCIS database (that contains the Round 1 monitoring results) and SDWIS/FED database (that contains the Round 2 monitoring results) were evaluated for completeness and quality. For both the URCIS (Round 1) and SDWIS/FED (Round 2) databases, some State data were unusable for a variety of reasons. Some States reported only detections, or the data were recorded with incorrect units. Data sets only including detections are obviously biased, over-representing high-occurrence settings. Other problems included substantially incomplete data sets without all PWSs reporting. Also, data from Washington, D.C. and the Virgin Islands were excluded from this analysis because it was difficult to evaluate them for the current purposes in relation to complete State data (USEPA, 2001a Sections II and III).

The balance of the States remaining after the data quality screening were then examined to establish a national cross-section. This step was based on evaluating the States’ pollution potential and geographic coverage in relation to all States. Pollution potential is considered to ensure a selection of States that represent the range of likely contaminant occurrence and a balance with regard to likely high and low occurrence. Geographic consideration is included so that the wide range of climatic and hydrogeologic conditions across the United States are represented, again balancing the varied conditions that affect transport and fate of contaminants, as well as conditions that affect naturally occurring contaminants (USEPA, 2001c Sections III.A. and III.B.).

The cross-section States were selected to represent a variety of pollution potential conditions. Two primary pollution potential indicators were used. The first factor selected indicates pollution potential from manufacturing/population density and serves as an indicator of the potential for VOC contamination within a State. Agriculture was selected as the second pollution potential indicator because the majority of SOCs of concern are pesticides (USEPA, 2001c Section III.A.). The 50 individual States were ranked

from highest to lowest based on the pollution potential indicator data. For example, the State with the highest ranking for pollution potential from manufacturing received a ranking of 1 for this factor and the State with the lowest value was ranked as number 50. States were ranked for their agricultural chemical use status in a similar fashion.

The States' pollution potential rankings for each factor were subdivided into four quartiles (from highest to lowest pollution potential). The cross-section States were chosen equally from all quartiles for both pollution potential factors to ensure representation, for example, from: States with high agrichemical pollution potential rankings and high manufacturing pollution potential rankings; States with high agrichemical pollution potential rankings and low manufacturing pollution potential rankings; States with low agrichemical pollution potential rankings and high manufacturing pollution potential rankings; and States with low agrichemical pollution potential rankings and low manufacturing pollution potential rankings (USEPA, 2001c Section III.B.). In addition, some secondary pollution potential indicators were considered to further ensure that the cross-section States included the spectrum of pollution potential conditions (high to low). At the same time, States within the specific quartiles were considered collectively across all quartiles to attempt to provide a geographic coverage across all regions of the United States.

The data quality screening, pollution potential rankings, and geographic coverage analysis established national cross-sections of 24 Round 1 (URCIS) States and 20 Round 2 (SDWIS/FED) States. In each cross-section, the States provide good representation of the nation's varied climatic and hydrogeologic regimes and the breadth of pollution potential for the contaminant groups (Table 3-3 and Figure 3-1).

3.3.1.2.2 Cross-Section Evaluation

To evaluate and validate the method for creating the national cross-sections, the method was used to create smaller State subsets from the 24-State, Round 1 cross-section. Again, States were chosen to achieve a balance from the quartiles describing pollution potential, and a balanced geographic distribution, to incrementally build subset cross-sections of various sizes. For example, the Round 1 cross-section was tested with subsets of 4, 8 (the first 4 State subset plus 4 more States), and 13 (8 State subset plus 5) States. Two additional cross-sections were included in the analysis for comparison; a cross-section composed of 16 States with biased data sets eliminated from the 24 State cross-section for data quality reasons and a cross-section composed of all 40 Round 1 States (USEPA, 2001c Section III.B.1).

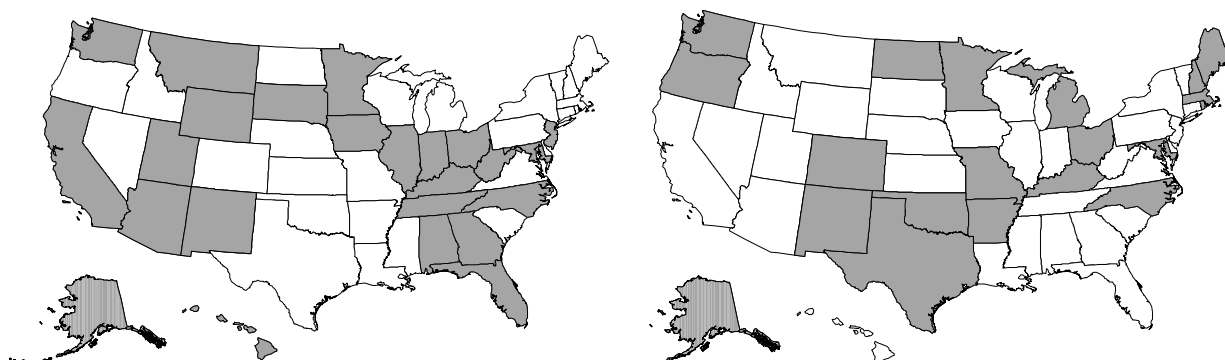
These Round 1 incremental cross-sections were then used to evaluate occurrence for an array of both high and low occurrence contaminants. The comparative results illustrate several points. The results are quite stable and consistent for the 8, 13 and 24 State cross-sections. They are much less so for the 4 State, 16 State (biased), and 40 State (all Round 1 States) cross-sections. The 4 State cross-section is apparently too small to provide balance both geographically and with pollution potential, a finding that concurs with past work (USEPA, 1999d). The CMR analysis suggested that a minimum of 6-7 States was needed to provide balance both geographically and with pollution potential, and the CMR report used 8 States out of the available data for its nationally representative cross-section. The 16 State and 40 State cross-sections, both including biased States, provided occurrence results that were unstable and inconsistent for a variety of reasons associated with their data quality problems (USEPA, 2001c Section III.B.1)

The 8, 13, and 24 State cross-sections provide very comparable results, are consistent, and are usable as national cross-sections to provide estimates of contaminant occurrence. Including greater data from more States improves the national representation and the confidence in the results—as long as the States are balanced related to pollution potential and spatial coverage. The 24 and 20 State cross-sections provide the most nationally representative cross-sections for the Round 1 and Round 2 data.

Table 3-3: Cross-section States for Round 1 (24 States) and Round 2 (20 States)

Round 1 (URCIS)		Round 2 (SDWIS/FED)	
Alabama	Minnesota*	Alaska*	New Hampshire
Alaska*	Montana	Arkansas	New Mexico*
Arizona	New Jersey	Colorado	North Carolina*
California	New Mexico*	Kentucky*	North Dakota
Florida	North Carolina*	Maine	Ohio*
Georgia	Ohio*	Maryland*	Oklahoma
Hawaii	South Dakota	Massachusetts	Oregon
Illinois	Tennessee	Michigan	Rhode Island
Indiana	Utah	Minnesota*	Texas
Iowa	Washington*	Missouri	Washington*
Kentucky*	West Virginia		
Maryland*	Wyoming		

* cross-section State in both Round 1 and Round 2

Figure 3-1: Geographic distribution of cross-section States for Round 1 (left) and Round 2 (right).

3.3.1.3 Data Management and Analysis

The cross-section analyses focused on occurrence at the water system level; i.e., the summary data presented discuss the percentage of public water *systems* with detections, not the percentage of *samples* with detections. By normalizing the analytical data to the system level, skewness inherent in the sample data, particularly over the multi-year period covered in the URCIS data, is avoided. System level analysis was used since a PWS with a known contaminant problem usually has to sample more frequently than a PWS that has never detected the contaminant. Obviously, the results of a simple computation of the percentage of samples with detections (or other statistics) can be skewed by the more frequent sampling results reported by the contaminated site. This level of analysis is conservative. For example, a system need only have a single sample with an analytical result greater than the MRL, i.e., a detection, to be counted as a system with a result “greater than the MRL.”

Also, the data used in the analyses were limited to only those data with confirmed water source and sampling type information. Only standard SDWA compliance samples were used; “special” samples, or “investigation” samples (investigating a contaminant problem that would bias results), or samples of unknown type were not used in the analyses. Various quality control and review checks were made of the results, including follow-up questions to the States providing the data. Many of the most intractable data quality problems encountered occurred with older data. These problematic data were, in some cases, simply eliminated from the analysis. For example, when the number of data with problems were insignificant relative to the total number of observations they were dropped from the analysis (For further details see Cadmus, 2000).

As indicated above, New Hampshire generally is included in the 20-State, Round 2 national cross-section. Naphthalene occurrence data from the State of New Hampshire, however, are biased. New Hampshire reports only 5 samples from three systems for Naphthalene with each system showing a detection. Though these results are simple detections not violating a health effect standard, and inclusion of the data does not significantly affect overall summary statistics, to maintain a consistent method for managing biased data, New Hampshire’s naphthalene data were omitted from Round 2 cross-section occurrence analyses and summaries presented in this report.

3.3.1.4 Occurrence Analysis

To evaluate national contaminant occurrence, a two-stage analytical approach has been developed. The first stage of analysis provides a straightforward, conservative, non-parametric evaluation of occurrence of the CCL regulatory determination priority contaminants as described above. These Stage 1 descriptive statistics are summarized here. Based in part on the findings of the Stage 1 Analysis, EPA will determine whether more rigorous parametric statistical evaluations, the Stage 2 Analysis, may be warranted to generate national probability estimates of contaminant occurrence and exposure for priority contaminants (for details on this two stage analytical approach see Cadmus, 2000, 2001).

The summary descriptive statistics presented in Table 3-4 for naphthalene are a result of the Stage 1 analysis and include data from both Round 1 (URCIS, 1987-1992) and Round 2 (SDWIS/FED, 1993-1997) cross-section States (minus New Hampshire). Included are the total number of samples, the percent samples with detections, the 99th percentile concentration of all samples, the 99th percentile concentration of samples with detections, and the median concentration of samples with detections. The percentages of PWSs and population served indicate the proportion of PWSs whose analytical results showed a detection(s) of the contaminant (simple detection, > MRL) at any time during the monitoring period; or a detection(s) greater than half the Health Reference Level (HRL); or a detection(s) greater than the Health Reference Level.

Naphthalene is not considered to be a linear carcinogen by the oral route of exposure. Accordingly, the Maximum Contaminant Level Goal (MCLG) is derived using a Reference Dose (RfD) approach. The value used as the Health Reference Level (HRL) for this occurrence evaluation is derived from the RfD using the following equation:

$$\text{HRL} = \frac{\text{RfD} \times \text{Body Weight}}{\text{Drinking Water Intake}} \times \text{Relative Source Contribution}$$

The body weight used in the calculation is an average adult body weight (70 Kg) and the value for daily water intake is 2 L. In the calculation of the HRL, the relative source contribution is 20%. A different relative source factor might be used to calculate the MCLG if a determination is made to regulate naphthalene.

The 99th percentile concentration is used here as a summary statistic to indicate the upper bound of occurrence values because maximum values can be extreme values (outliers) that sometimes result from sampling or reporting error. The 99th percentile concentration is presented for both the samples with only detections and all of the samples because the value for the 99th percentile concentration of all samples is below the MRL (denoted by "<" in Table 3-4). For the same reason, summary statistics such as the 95th percentile concentration of all samples or the median (or mean) concentration of all samples are omitted because these also are all "<" values. This is the case because only 0.43% and 0.23% of all samples recorded detections of naphthalene in Round 1 and Round 2, respectively.

As a simplifying assumption, a value of half the MRL is often used as an estimate of the concentration of a contaminant in samples/systems whose results are less than the MRL. With a contaminant with relatively low occurrence such as naphthalene in drinking water occurrence databases, the median or mean value of occurrence using this assumption would be half the MRL ($0.5 \times \text{MRL}$). However, for these occurrence data this is not straightforward. For Round 1 and Round 2, States have reported a wide range of values for the MRLs. This is in part related to State data management differences as well as real differences in analytical methods, laboratories, and other factors.

The situation can cause confusion when examining descriptive statistics for occurrence. For example, for Round 2 most States reported non-detections as zeros resulting in a modal MRL value of zero. By definition the MRL cannot be zero. This is an artifact of State data management systems. Because a simple meaningful summary statistic is not available to describe the various reported MRLs, and to avoid confusion, MRLs are not reported in the summary table (Table 3-4).

In Table 3-4, national occurrence is estimated by extrapolating the summary statistics for the 24 and 20 State cross-sections (minus New Hampshire) to national numbers for systems, and population served by systems, from the *Water Industry Baseline Handbook, Second Edition* (USEPA, 2000g). From the handbook, the total number of CWSs plus NTNCWSs is 65,030, and the total population served by CWSs plus NTNCWSs is 213,008,182 persons (see Table 3-4). To generate the estimate of national occurrence based on the cross-section occurrence findings, the national number of PWSs (or population served by PWSs) is simply multiplied by the percentage value for the particular cross section occurrence statistic [e.g., the national estimate for the total number of PWSs with detections (769) is the product of the total number of PWSs (65,030) and the percentage of PWSs with detections (1.18%) and the national estimate for the total number of PWSs (65,030)].

Because the State data used for the cross-section are not a strict statistical sample, national extrapolations of these Stage 1 analytical results can be problematic, especially for contaminants with very low occurrence like naphthalene and other CCL regulatory determination priority contaminants. For this reason, the nationally extrapolated estimates of occurrence based on Stage 1 results are not presented in the *Federal Register* Notice. The presentation in the *Federal Register* Notice of only the actual results of the cross-section analysis maintains a straight-forward presentation, and the integrity of the data, for stakeholder review. The nationally extrapolated Stage 1 occurrence values are presented here, however, to provide additional perspective. A more rigorous statistical modeling effort, the Stage 2 analysis, could be conducted on the cross-section data (Cadmus, 2001). The Stage 2 results would be more statistically robust and more suitable to national extrapolation. This approach would provide a probability estimate and would also allow for better quantification of estimation error.

Round 1(1987-1992) and Round 2 (1993-1997) data were not merged because they represent different time periods, different States (only eight States are represented in both rounds), and each round has different data management and data quality problems. The two rounds are only merged for the simple spatial analysis overview presented in Section 3.3.2.2 and Figures 3-2 and 3-4.

3.3.2 Results

3.3.2.1 Occurrence Estimates

While States with detections of naphthalene are widespread (Figure 3-2), the percentages of PWSs by State with detections are modest (Table 3-4). In aggregate, the cross-sections show approximately 0.8% to 1.2% of PWSs in both rounds experienced detections ($>$ MRL), affecting 3.0% to 4.8% of the population served (approximately 6 - 10 million people). Percentages of PWSs with detections greater than half the Health Reference Level ($>$ $\frac{1}{2}$ HRL) are much lower for both rounds: 0.01%. The percentage of PWSs exceeding the Health Reference Level ($>$ HRL) is also very small (see also Figure 3-4). Detections greater than the HRL were only reported in Round 1: 0.01% of PWSs, affecting a population of approximately 16,000.

Note that for the Round 1 cross-section, the total number of PWSs (and the total population served by the PWSs) is not the sum of the number of ground water and surface water systems (or the populations served by those systems). Because some public water systems are seasonally classified as either surface or ground water, some systems may be counted in both categories. The population numbers for the Round 1 cross-section are also incomplete. Not all of the PWSs for which occurrence data was submitted reported the population they served. (However, the population numbers presented in Table 3-4 for the Round 1 cross-section are reported from approximately 95% of the systems.)

The national estimates extrapolated from Round 1 and Round 2 PWS numbers and populations are not additive either. In addition to the Round 1 classification and reporting issues outlined above, the proportions of surface water and ground water PWSs, and populations served by them, are different between the Round 1 and 2 cross-sections and the national estimates. For example, approximately 63% of the population served by PWSs in the Round 2 cross-section States are served by surface water PWSs (Table 3-4). Nationally, however, that proportion changes to 60%.

Both Round 1 and Round 2 national cross-sections show a proportionate balance in PWS source waters compared to the national inventory. Nationally, 91% of PWSs use ground water (and 9% of surface water); Round 1 shows 89% and Round 2 shows 90% of systems using ground water. The relative populations served are not as closely comparable. Nationally, about 40% of the population is served by PWSs using ground water (and 60% by surface water). Round 2 data is most representative with 37% of the cross-section population served by ground water; Round 1 shows about 55%.

There are differences in the occurrence results between Round 1 and Round 2, as should be expected. The differences are not great, however, particularly when comparing the proportions of systems affected. The results range from 0.8% to 1.2% of PWSs with detections of naphthalene and range from 0.00% to 0.01% of PWSs with detections greater than the HRL of 140 $\mu\text{g/L}$. These are not substantively different, given the data sources. The differences in the population extrapolations appear greater, but still constitute relatively small proportions of the population. Less than 5.0% of the population served by PWSs in either round are served by systems with detections and only 0.01% of the population served by Round 1 PWSs were served by systems with detections greater than the HRL.

The Round 2 cross-section provides a better proportional balance related to the national population of PWSs and may have fewer reporting problems than Round 1. The non-zero estimate of the national population served by PWSs with detections greater than the HRL using Round 1 data can also provide an upper bound estimate in considering the data.

Table 3-4: Summary occurrence statistics for naphthalene

Frequency Factors	24 State Cross-Section¹ (Round 1)	20 State Cross-Section² (Round 2)	National System & Population Numbers³	
Total Number of Samples	45,567	94,910	--	
Percent of Samples with Detections	0.43%	0.23%	--	
99 th Percentile Concentration (all samples)	< (Non-detect)	< (Non-detect)	--	
Health Reference Level	140 µg/L	140 µg/L	--	
Minimum Reporting Level (MRL)	Variable ⁴	Variable ⁴	--	
99 th Percentile Concentration of Detections	900 µg/L	73 µg/L	--	
Median Concentration of Detections	1.0 µg/L	0.73 µg/L	--	
Total Number of PWSs	13,452	22,923	65,030	
Number of GW PWSs	12,034	20,524	59,440	
Number of SW PWSs	1,502	2,399	5,590	
Total Population	77,209,916	67,498,059	213,008,182	
Population of GW PWSs	42,218,746	25,185,032	85,681,696	
Population of SW PWSs	41,987,010	42,313,027	127,326,486	
Occurrence by System			National Extrapolation⁵	
			Round 1	Round 2
% PWSs with detections (> MRL)	1.18%	0.75%	769	491
Range of Cross-Section States	0 - 28.24%	0 - 4.48%	N/A	N/A
GW PWSs with detections	1.08%	0.62%	642	368
SW PWSs with detections	1.93%	1.92%	108	107
% PWSs > 1/2 Health Reference Level (HRL)	0.01%	0.01%	10	6
Range of Cross-Section States	0 - 1.53%	0 - 0.06%	N/A	N/A
GW PWSs > 1/2 Health Reference Level	0.02%	0.01%	10	6
SW PWSs > 1/2 Health Reference Level	0.00%	0.00%	0	0
% PWSs > Health Reference Level	0.01%	0.00%	10	0
Range of Cross-Section States	0 - 1.53%	0.00%	N/A	N/A
GW PWSs > Health Reference Level	0.02%	0.00%	10	0
SW PWSs > Health Reference Level	0.00%	0.00%	0	0
Occurrence by Population Served				
% PWS Population Served with detections	2.910%	4.790%	6,198,000	10,204,000
Range of Cross-Section States	0 - 37.22%	0 - 31.41%	N/A	N/A
GW PWS Population with detections	4.005%	1.162%	3,431,000	995,000
SW PWS Population with detections	1.323%	6.950%	1,685,000	8,849,000
% PWS Population Served > 1/2 Health Reference Level	0.007%	0.002%	16,000	5,000
Range of Cross-Section States	0 - 0.23%	0 - 0.01%	N/A	N/A
GW PWS Population > 1/2 Health Reference Level	0.013%	0.007%	11,000	6,000
SW PWS Population > 1/2 Health Reference Level	0.000%	0.000%	0	0
% PWS Population Served > Health Reference Level	0.007%	0.000%	16,000	0
Range of Cross-Section States	0 - 0.23%	0.000%	N/A	N/A
GW PWS Population > Health Reference Level	0.013%	0.000%	11,000	0
SW PWS Population > Health Reference Level	0.000%	0.000%	0	0

1. Summary Results based on data from 24-State Cross-Section, from URCIS, UCM (1987) Round 1.

2. Summary Results based on data from 20-State Cross-Section (minus New Hampshire), from SDWIS/FED, UCM (1993) Round 2.

3. Total PWS and population numbers are from EPA March 2000 Water Industry Baseline Handbook.

4. See Section 3.3.1.4 for discussion

5. National extrapolations are from the 24-State data and 20-State data using the Baseline Handbook system and population numbers.

- PWS = Public Water Systems; GW = Ground Water; SW = Surface Water; MRL = Minimum Reporting Level (for laboratory analyses);

- HRL = Health Reference Level, an estimated health effect level used for preliminary assessment for this review; N/A = Not Applicable

- The Health Reference Level used for naphthalene is 140 µg/L. This is a draft value for working review only.

- Total Number of Samples = the total number of analytical records for naphthalene.

- 99th Percentile Concentration = the concentration value of the 99th percentile of either all analytical results or just the samples with detections (in µg/L).

- Median Concentration of Detections = the median analytical value of all the detections (analytical results greater than the MRL (in µg/L).

- Total Number of PWSs = the total number of public water systems with records for naphthalene.

- Total Population Served = the total population served by public water systems with records for naphthalene.

- % PWS with detections, % PWS > 1/2 Health Reference Level, % PWS > Health Reference Level = percent of the total number of public water systems with at least one analytical result that exceeded the MRL, 1/2 Health Reference Level, Health Reference Level, respectively.

3.3.2.2 Regional Patterns

Occurrence results are displayed graphically by State in Figures 3-2, 3-3, and 3-4 to assess whether any distinct regional patterns of occurrence are present. Combining Round 1 and Round 2 data (Figure 3-2), there are forty-seven States reporting. Four of those States have no data for naphthalene, while another 11 have no detections of the chemical. The remaining 32 States have detected naphthalene in drinking water and are well distributed throughout the United States. In contrast to the summary statistical data presented in the previous section, this simple spatial analysis includes the biased New Hampshire data.

The simple spatial analysis presented in Figures 3-2, 3-3, and 3-4 suggests that special regional analyses are not warranted because naphthalene occurrence at concentrations below the HRL is widespread. While no clear geographical patterns of occurrence are apparent, comparisons with environmental use and release information are useful (see also Section 3.1.2). The 47 TRI States reporting releases of naphthalene to the environment include all of the States that detected it in drinking water except New Hampshire. Also, four of the six States that have not detected naphthalene in site samples reported to ATSDR's HazDat database, and three of the six States where it was not detected at CERCLA NPL sites, have detected it in drinking water.

Figure 3-2: States with PWSs with detections of naphthalene for all States with data in URCIS (Round 1) and SDWIS/FED (Round 2)

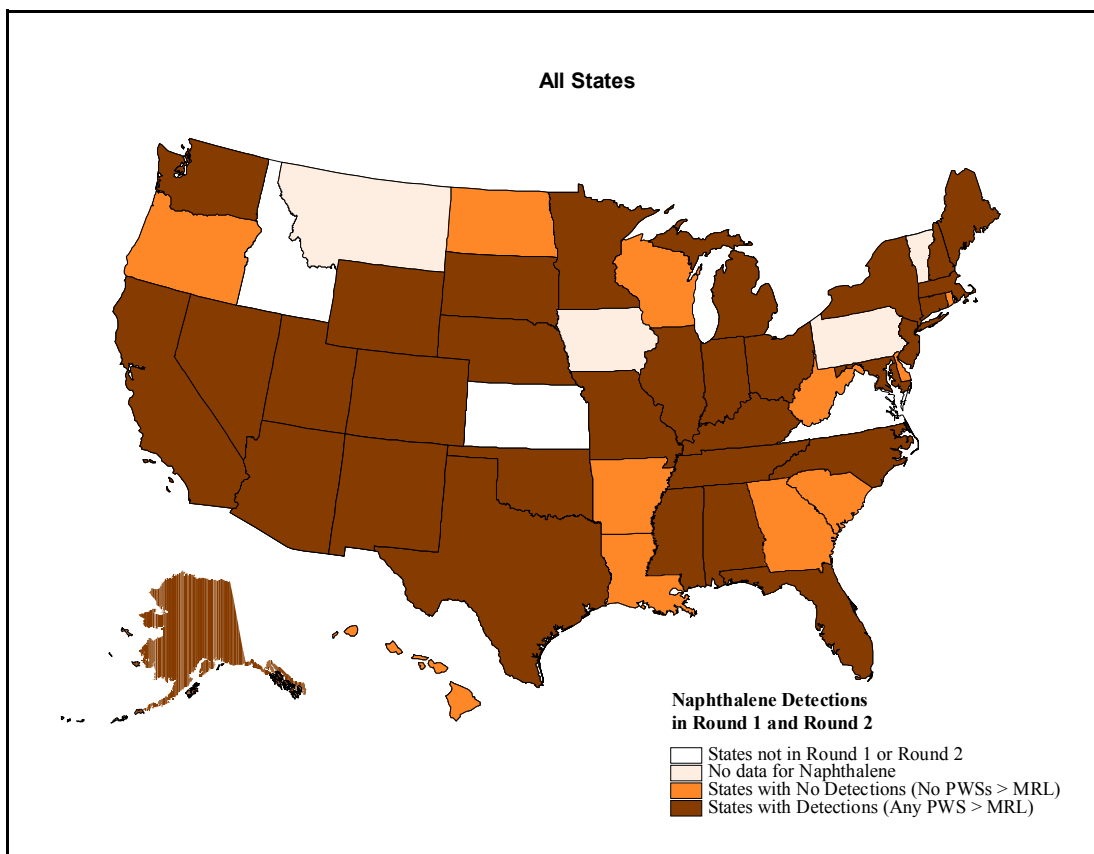


Figure 3-3: States with PWSs with detections of naphthalene (any PWSs with results greater than the Minimum Reporting Level [MRL]) for Round 1 (above) and Round 2 (below) cross-section States

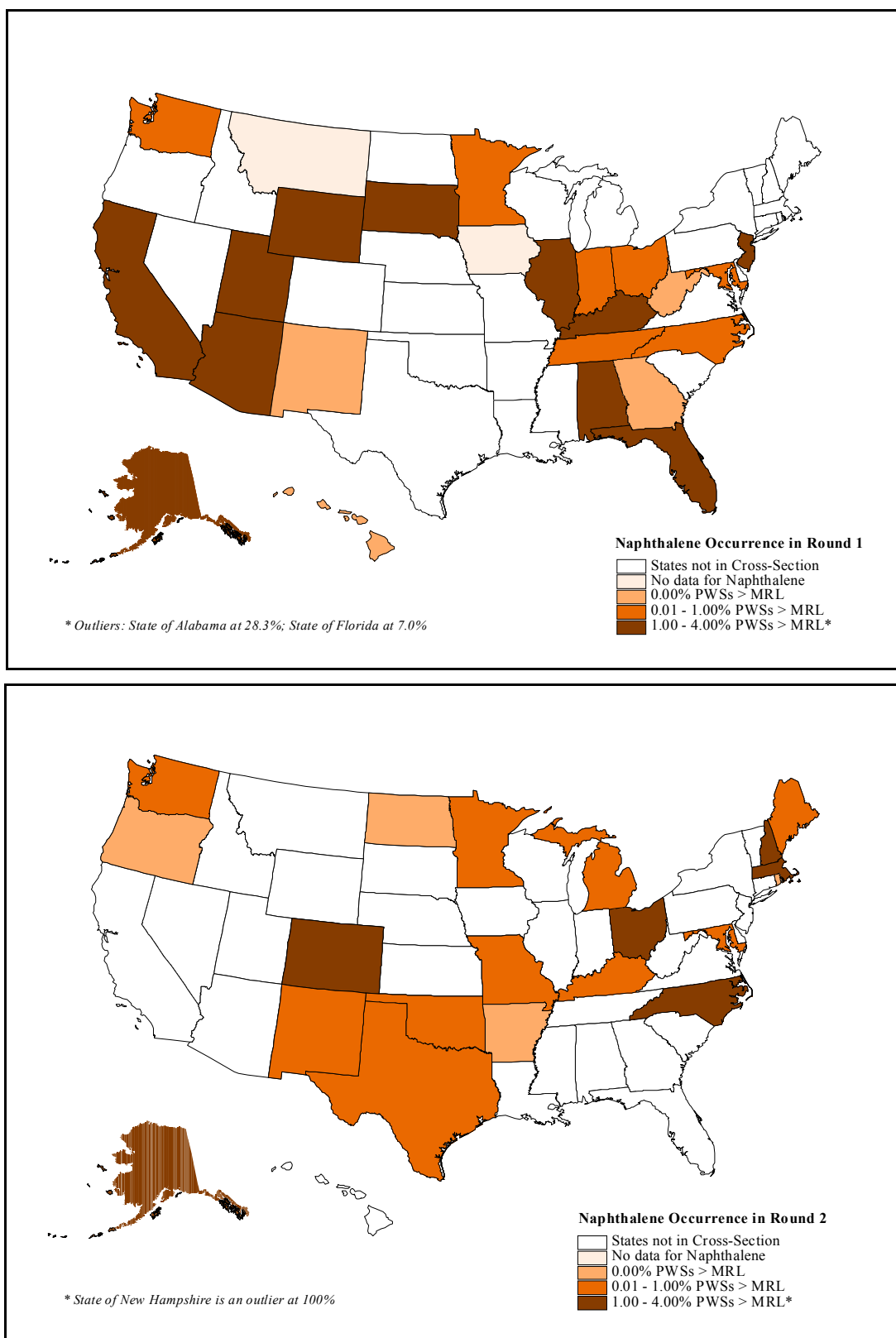
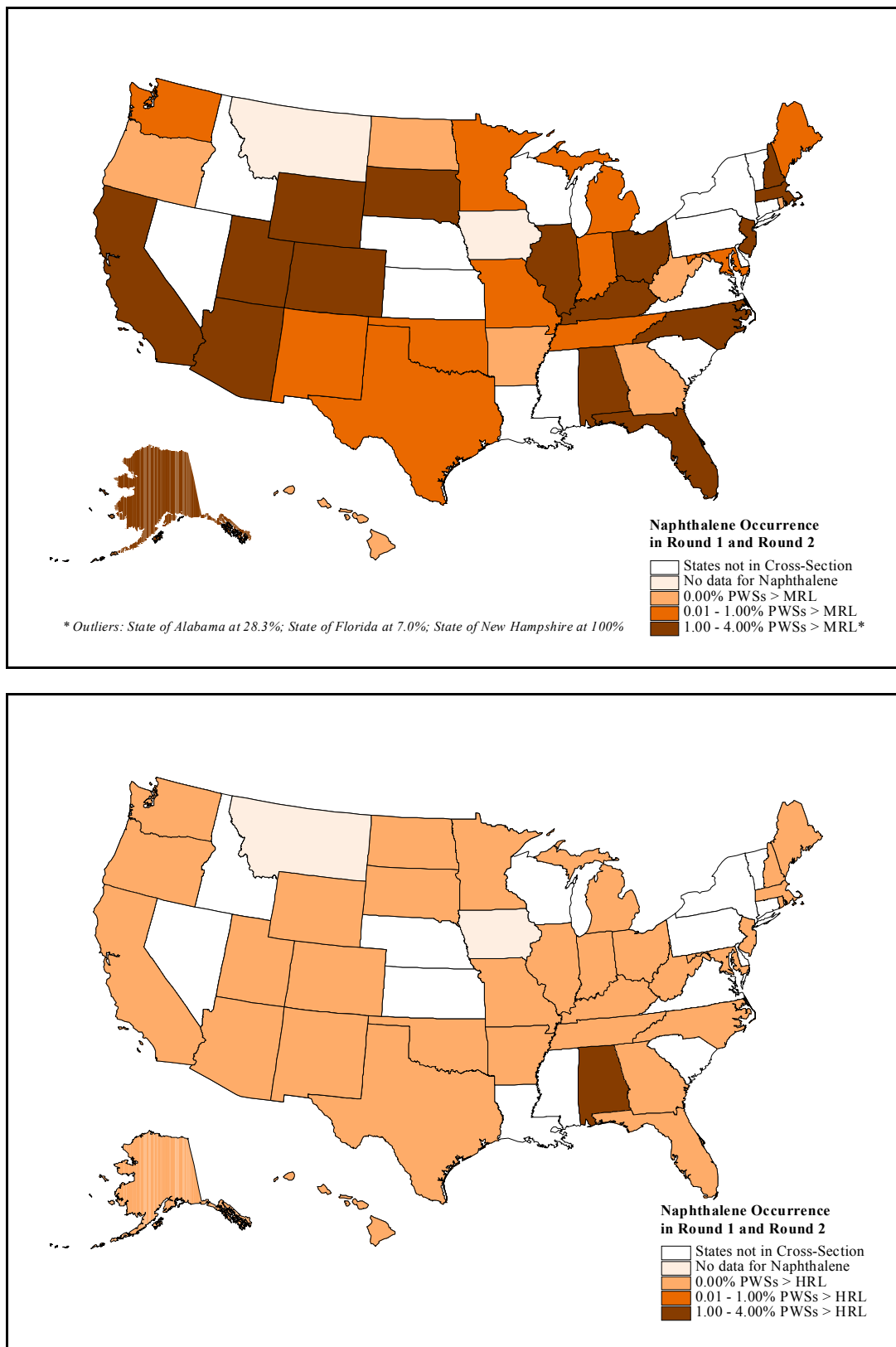


Figure 3-4: Cross-section States (Round 1 and Round 2 combined) with PWSs with detections of naphthalene (above) and concentrations greater than the Health Reference Level (below)



3.4 Conclusion

Naphthalene has been detected in untreated ambient ground water samples reviewed and/or analyzed by the USGS NAWQA program. Detection frequencies and concentrations for all wells are relatively low; however, occurrence is considerably higher for urban wells when compared to rural wells. Naphthalene has been detected at slightly higher frequencies in urban and highway runoff. Concentrations in runoff are low, with maximum concentrations well below the current HAL of 100 µg/L. Naphthalene has also been found at ATSDR HazDat and CERCLA NPL sites across the country and releases have been reported through the Toxic Release Inventory.

Naphthalene has also been detected in PWS samples collected under SDWA. Occurrence estimates are low for Round 1 and Round 2 monitoring with only 0.43% and 0.23% of all samples showing detections, respectively. Significantly, the values for the 99th percentile and median concentrations of all samples are less than the MRL. For Round 1 samples with detections, the median concentration is 1.0 µg/L and the 99th percentile concentration is 900 µg/L. Median and 99th percentile concentrations for Round 2 detections are 0.73 µg/L and 73 µg/L, respectively. Systems with detections constitute only 1.2% of Round 1 systems and 0.8% of Round 2 systems (an estimate of 769 (Round 1) and 491 (Round 2) systems nationally). National estimates for the population served by PWSs with detections are also low, especially for detections greater than the HRL. It is estimated that less than 0.01% of the national PWS population is served by systems with detections greater than the HRL (approximately 16,000 people).

In summary, the occurrence data indicate that naphthalene is infrequently detected in ambient waters or public water systems in the United States. Furthermore, when naphthalene is detected, it very rarely exceeds the HRL or a value of one-half of the HRL. Therefore, in relation to the key determination criterion the occurrence data indicate that naphthalene does not occur in public water systems with a frequency, or at levels, of public health concern.

4.0 HEALTH EFFECTS

A full description of the health effects and the dose-response information for threshold and non-threshold effects associated with exposure to naphthalene are presented in Chapters 7 and 8 of the *Health Effects Support Document for Naphthalene* (USEPA, 2001b). A summary of the pertinent findings are presented below.

4.1 Hazard Characterization and Mode of Action Implications

Data for the human health effects of naphthalene are limited. Medical case reports of accidental and intentional ingestion identify hemolytic anemia (breakdown of red-blood cells) and cataracts as significant outcomes of oral exposure in humans. Case reports of individuals (primarily infants) exposed to naphthalene via dermal contact, inhalation, or a combination of both exposure routes point to hemolytic anemia and its consequences such as jaundice and enlargement of the spleen as the most commonly manifested toxic effects in humans following exposure at concentrations that exceed average environmental levels. There are no reliable human toxicity data for subchronic or chronic exposure to naphthalene.

In animals, acute or subchronic exposure to relatively high oral doses (200 to 700 mg/kg or greater) of naphthalene resulted in hemolytic anemia (dogs only) and cataracts (rats and rabbits). Lower oral doses of naphthalene (less than 200 to 400 mg/kg) administered to rats and mice in three subchronic studies resulted in decreased body weight, central nervous system depression, and altered organ weights, but did not result in hemolytic anemia or cataracts. No treatment-related lesions were observed in studies

reporting histopathology. A limitation of the health effects database for naphthalene is the lack of adequately designed chronic oral exposure studies in animals.

There is no evidence of developmental effects in animals after exposure to naphthalene doses of 120 mg/kg or less. Developmental studies at higher doses produced inconsistent results with regard to maternal and fetal effects.

The available data for mode of action indicate that oxidative metabolism of naphthalene following oral or inhalation exposure produces a variety of reactive metabolites. These metabolites subsequently react with cellular macromolecules such as those in cell membranes or enzymes to elicit toxicity in target tissues such as the blood, eye, and (in animal inhalation studies) nose and lung. Direct exposure of the cells lining the respiratory tract causes inflammation, tissue damage, and reparative cell division. Although naphthalene does not appear to be directly genotoxic, long term inhalation exposure of mice and rats has caused development of adenomas (benign tumors) and carcinomas in the nasal cavity (rats) and lungs (female mice). Naphthalene does not appear to be carcinogenic by the oral route.

People with impaired cellular defense capabilities may be more susceptible to naphthalene toxicity. The finding that individuals deficient in the enzyme glucose-6-phosphate dehydrogenase (G6PD) are more likely to develop hemolytic anemia following exposure to naphthalene confirms this prediction and identifies this group as a potentially susceptible population. Individuals with this deficiency have lower levels of reduced glutathione, a compound which normally protects red blood cells against oxidative damage. G6PD-deficient neonates, infants, and the fetus are particularly sensitive to naphthalene toxicity because the metabolic pathways responsible for detoxification of reactive naphthalene metabolites are not yet well developed. In addition, these groups have low levels of methemoglobin reductase, increasing their vulnerability in the period immediately after birth. Methemoglobin is a form of hemoglobin in which the iron has been changed so that the red blood cell can no longer carry oxygen. Naphthalene and other chemicals can change the iron in hemoglobin from its +2 to its +3 state causing methemoglobinemia. The enzyme methemoglobin reductase is responsible for returning the iron in hemoglobin to its normal +2 state and restoring the ability to bind with oxygen.

4.2 Dose-Response Characterization and Implications in Risk Assessment

Information on the human health effects of naphthalene has been obtained from medical case reports of intentional or accidental ingestion. The usefulness of case study data for assessing risk from drinking water ingestion are limited by one or more of the following factors: quantitative exposure data are not available in most case reports; the toxicokinetics of a single large dose may differ from those of chronic low-level exposure; and/or the low aqueous solubility of naphthalene may prevent the occurrence of concentrations in drinking water that are comparable to the doses that require medical attention. The limited human exposure data from case reports suggest that cataracts occurred following a single dose of approximately 71 mg/kg consumed over 13 hours (Lezenius, 1902). Indications of hemolytic anemia resulted after a single oral dose of approximately 109 mg/kg (Gidron and Leurer, 1956).

All available dose-response information for naphthalene toxicity in animals is extensively summarized in Table 7-7 in the *Health Effects Support Document for Naphthalene* (USEPA, 2001b). Five key studies are summarized below. These five studies currently provide the most reliable information on threshold levels for naphthalene toxicity in animals exposed via the oral route. Included in this group are two short-term studies and three subchronic studies. There are presently no adequately designed chronic oral exposure studies.

In short-term studies, a Lowest Observed Adverse Effect Level (LOAEL) of 50 mg/kg-day (the lowest dose tested) was identified for transient signs of neurotoxicity (i.e. slowed respiration and

movement) in pregnant rats administered naphthalene on gestation days 6–15 (NTP, 1991). A No Observed Adverse Effect Level (NOAEL) of 53 mg/kg-day and LOAEL of 267 mg/kg-day were identified for effects on body weight and organ weight observed in a 14-day study conducted in mice (Shopp et al., 1984). In subchronic studies, NOAEL and LOAEL values of 100 mg/kg-day and 200 mg/kg-day, respectively, were identified in 13-week studies conducted in rats and mice (BCL, 1980a, b). The corresponding duration-adjusted values are 71 mg/kg-day and 143 mg/kg-day, respectively. The LOAEL in rats was identified on the basis of decreased terminal body weight, while the LOAEL in mice was identified on the basis of transient clinical signs of toxicity observed during weeks 3 to 5 of the study. In the third subchronic study, NOAEL and LOAEL values of 53 mg/kg-day and 133 mg/kg-day, respectively, were identified on the basis of changes in organ weights and data suggestive of changes in enzyme activity observed in mice administered naphthalene for 90 days (Shopp et al., 1984).

For hemolytic anemia and cataracts (the endpoints of greatest relevance to humans), the available animal data are limited by deficiencies in study design, including the use of a single high dose (typically 500 to 2,000 mg/kg-day) and/or an inadequate number of test animals. NOAEL and LOAEL values therefore cannot be identified in these studies. Holmen et al. (1999) identified a LOAEL of 500 mg/kg-day for ocular changes in a multidose study where rats were dosed twice weekly for 10 weeks.

To place short-term and subchronic dose-response information in perspective, a high-end estimate of naphthalene intake can be calculated. The solubility of naphthalene in water is 31 mg/L. Assuming that naphthalene is present at the limit of solubility, the dose to a 70 kg adult consuming 2 L of drinking water per day would be 0.9 mg/kg-day. The dose to a 10 kg child consuming 1 L of drinking water per day would be 3.1 mg/kg-day. Comparison of these doses to the threshold levels for naphthalene toxicity indicates that the human LOAEL values are at least an order of magnitude greater than the estimated high-end dose.

The Reference Dose (RfD) for naphthalene is 2×10^{-2} mg/kg-day (USEPA, 1998c). The RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime. Because there are no adequate chronic oral exposure studies for naphthalene, the RfD is based on a NOAEL of 71 mg/kg-day identified for lack of effect on terminal body weight in male rats orally exposed to naphthalene for 13 weeks (BCL, 1980a). An uncertainty factor of 3,000 was used in the derivation of the RfD to account for use of a subchronic study (factor of 10), extrapolation from humans to animals (factor of 10), variability in human populations (factor of 10), and lack of multidose studies in species that are sensitive to hemolytic anemia and cataracts (factor of 3). The derivation of the RfD for naphthalene is discussed in Section 8.1.1 of the Drinking Water Support Document for Naphthalene (USEPA, 2001b).

The Reference Concentration (RfC) for naphthalene is 3×10^{-3} mg/m³ (USEPA, 1998c). The RfC is an estimate (with uncertainty spanning perhaps an order of magnitude) of a continuous inhalation dose to the human population (including sensitive subgroups) that is likely to be without appreciable risk of adverse effects over a lifetime of exposure. The RfC for naphthalene is based on lesions of the nose observed in a chronic inhalation study of naphthalene in mice (NTP, 1992). Details of the RfC derivation are provided in Section 8.1.6 of the *Health Effects Support Document for Naphthalene* (USEPA, 2001b). Comparison of inhalation doses to the RfC can be useful in the risk assessment of contaminants that readily volatilize from drinking water during household activities. In the case of naphthalene, volatilization from water is expected to be minimal.

No quantitative dose-response analysis (including dose-conversion, extrapolation methods, oral slope factor or inhalation unit risk) for cancer is presented at this time due to the weakness of evidence that naphthalene may be carcinogenic in humans.

4.3 Relative Source Contribution

Relative source contribution analysis compares the magnitude of exposure expected via drinking water to the magnitude of exposure from intake of naphthalene in other media such as food, air, and soil. To perform this analysis, intake of naphthalene from drinking water must be estimated. Drinking water occurrence data for naphthalene are presented in Section 3.3. The median and 99th percentile concentrations for naphthalene were below the MRL when all samples (i.e., those with detectable and nondetectable levels of naphthalene) from either Round 1 or Round 2 were analyzed.

As a simplifying assumption, a value of one-half of the MRL is often used as an estimate of the concentration of a contaminant when the results are less than the MRL. Because a single estimate of the MRL for naphthalene was unavailable [see Section 5.4.1 of the *Health Effects Support Document for Naphthalene* (USEPA, 2001b)], two alternative approaches were used to estimate average daily intakes from drinking water. The reported detection limits for naphthalene range from 0.01 µg/L for the most sensitive to 3.3 µg/L for the least sensitive methods (ATSDR, 1995). If a value of one-half the detection limit is used as a rough estimate of the concentration of naphthalene, this equates to a range of 0.005 to 1.65 µg/L. Assuming intake of 2 L/day of drinking water by a 70 kg adult, the average daily dose would be 1.4×10^{-3} to 47.1×10^{-3} µg/kg-day (1.4 to 47.1 ng/kg-day). The corresponding dose for a 10 kg child consuming 1 L/day of drinking water would be 0.5×10^{-3} to 165×10^{-3} µg/kg-day (0.5 to 165 ng/kg-day). Alternatively, if the median concentration for naphthalene in samples with detectable levels (approximately 1 µg/L) is used, the average daily doses to an adult and child would be 28.6×10^{-3} and 100×10^{-3} µg/kg-day (28.6 and 100 ng/kg-day), respectively.

Collectively, available data indicate that intake from drinking water will often be relatively low when compared to intake from other media. The estimated average daily intakes of naphthalene from drinking water (based on median detected concentrations) and other media were used to calculate estimated ratios of the exposure from each medium to the exposure from water. The estimated food:drinking water exposure ratio ranges from 1 to 8 for an adult and from 2 to 9 for a child. The estimated air:drinking water exposure ratio is 39 for an adult and 45 for a child. The range of estimated naphthalene intake from soil is very broad for both children and adults; thus the soil water intake ratio will be highly scenario-dependent. For an adult, the estimated soil:drinking water exposure ratio ranges from less than 1 to 103. For a child, the estimated soil:drinking water exposure ratio ranges from 2 to 430.

4.4 Sensitive Populations

The sensitive populations identified for naphthalene include individuals (including infants, neonates and the fetus) deficient in the enzyme glucose-6-phosphate dehydrogenase (G6PD). This enzyme helps protect red blood cells from oxidative damage. The enzyme deficiency makes red blood cells more sensitive to a variety of toxins, including naphthalene. Thus, the hemolytic response to naphthalene is enhanced in G6PD-deficient individuals. Higher rates of inherited G6PD deficiency are found among the people of Asia, Greece, Italy, the Middle East, and Africa. In the United States, an estimated 5.2% to 11.5% of the population has an inherited G6PD deficiency (Luzzatto and Mehta, 1989). Because this defect is linked to the X-chromosome, males are more likely to be affected than females.

New-born infants are generally considered to be more sensitive to naphthalene toxicity because the metabolic pathways for conjugation of naphthalene are not well developed. New-born infants also have low levels of methemoglobin reductase, which may compound and prolong some effects of hemolytic anemia.

Calculation of medium-specific exposure ratios indicates that naphthalene intake from air is about 40-fold greater than intake from water. Naphthalene intakes from food and soil may also be significantly

greater (up to 9-fold greater and 430-fold greater for a child, respectively) than from water, depending on the exposure scenario. Therefore, regulation of naphthalene in drinking water would be unlikely to significantly reduce the risk to sensitive populations.

4.5 Exposure and Risk Information

Approximately 6 to 10 million people are served by systems with detections greater than the MRL. An estimated 5,000 of these individuals may be served by systems with detections greater than one-half the HRL based on Round 2 monitoring data, but exposures above the HRL would be rare and localized. Prevalence data for G6PD deficiency in the United States indicate that 5.2% to 11.5% of the exposed individuals may have reduced activity of G6PD and, thus, have an increased risk for methemoglobinemia and possibly hemolytic anemia if exposed to moderate-to-high doses of naphthalene. Methemoglobinemia is a precursor event to hemolysis induced by naphthalene, as well as by a variety of other chemical agents. Hemolytic anemia is an acute effect that is precipitated when the oxidative damage to the red blood cell is sufficient to cause breakdown of the cell membrane. Neonates and infants have reduced protection against methemoglobinemia due to developmental delays in the activity of methemoglobin reductase, a protective enzyme.

Hemolytic anemia is an acute effect that occurs at moderate-to-high doses of naphthalene. When average daily intakes from drinking water are compared with intakes from food, air and soil, drinking water accounts for a relatively small proportion of total naphthalene intake. On the basis of these observations, the impact of regulating naphthalene concentrations in drinking water on health risk is likely to be small.

4.6 Conclusion

In conclusion, while there is evidence that naphthalene may have adverse health effects in humans at high doses, it is unlikely that it will occur in drinking water at frequencies or concentrations that are of public health concern. There are inadequate data to support a conclusion about the carcinogenicity of naphthalene by the oral route of exposure. All preliminary CCL regulatory determinations and further analysis will be presented in the *Federal Register* Notice.

5.0 TECHNOLOGY ASSESSMENT

If a determination has been made to regulate a contaminant, SDWA requires development of proposed regulations within 2 years of making the decision. It is critical to have suitable monitoring methods and treatment technologies to support regulation development according to the schedules defined in the SDWA.

5.1 Analytical Methods

The availability of analytical methods does not influence EPA's determination of whether or not a CCL contaminant should be regulated. However, before EPA actually regulates a contaminant and establishes a Maximum Contaminant Level (MCL), there must be an analytical method suitable for routine monitoring. Therefore, EPA needs to have approved methods available for any CCL regulatory determination contaminant before it is regulated with an NPDWR. These methods must be suitable for compliance monitoring and should be cost effective, rapid, and easy to use.

Naphthalene is an unregulated contaminant for which monitoring was required under the Unregulated Contaminant Monitoring program (USEPA, 1987; 52 FR 25690). It already has well-documented analytical methods developed specifically for low-level drinking water analyses.

For naphthalene, there are two analytical methods available. EPA Method 524.2 is a well established, and sensitive, purge and trap gas chromatographic/mass spectrometry (GC/MS) method with a detection limit of 0.04 µg/L. EPA Method 502.2, a purge and trap method using conventional gas chromatography detectors (PID and ELCD in series), has a method detection limit of 0.02 µg/L.

5.2 Treatment Technology

Treatment technologies also do not influence the determination of whether or not a contaminant should be regulated. But before a contaminant can be regulated with an NPDWR, treatment technologies must be readily available. EPA's Office of Research and Development (ORD) has researched treatment technologies for all of the organic compounds listed as regulatory determination priorities on the CCL, including naphthalene. The two appropriate technologies reviewed were granular activated carbon (GAC) and air stripping.

Granular activated carbon treatment removes contaminants via the physical and chemical process of sorption, by which the contaminants attach to the carbon surface as water passes through the carbon bed. Activated carbon has a large sorption capacity for many water impurities including synthetic organic contaminants, taste and odor causing compounds, and some species of mercury. Adsorption capacity is typically represented by the Freundlich isotherm constants, with higher Freundlich K values indicating greater sorption potential.

Air stripping involves the continuous contact of air with the water being treated, allowing volatile dissolved contaminants to transfer from the source water to the air. After contact, the "contaminated air" is swept from the system, taking the contaminant out of contact with the treated water. The driving force for the water-to-air transfer of the volatile contaminants is the contaminant's concentration gradient between the water and air. The Henry's Law constant is a commonly used indicator of the tendency of a contaminant to partition from water to air. A larger Henry's constant indicates a greater equilibrium of the contaminant in the air. Thus, contaminants having larger Henry's constant are more easily removed by air stripping.

Predictive computer modeling and specific chemical characteristics were used to determine the isotherm constants needed to evaluate the two treatment technologies. The rule of thumb used for SDWA compounds, learned through the development of cost-and-technology documents to support other drinking water regulations, is that GAC is considered to be cost-effective if the contaminant has a Freundlich (K) value above 200 (Speth and Adams, 1993). For air stripping, a compound with a Henry's constant above dibromochloropropane (0.005) or ethylene dibromide (0.037) is considered strippable at a reasonable cost.

Naphthalene has a predicted Freundlich (K) value of 25,000, so it can be effectively treated by the GAC method. However, because its predicted Henry's Law constant is 0.02, naphthalene can only undergo effective air stripping procedures under certain concentration conditions.

6.0 SUMMARY AND CONCLUSIONS - DETERMINATION OUTCOME

Three statutory criteria are used to guide the determination of whether regulation of a CCL contaminant is warranted: 1) the contaminant may adversely affect the health of persons; 2) the

contaminant is known or is likely to occur in public water systems with a frequency, and at levels, of public health concern; and 3) regulation of the contaminant presents a meaningful opportunity for health risk reduction for persons served by public water systems. As required by SDWA, a decision to regulate a contaminant commits the EPA to propose a Maximum Contaminant Level Goal (MCLG) and promulgate a National Primary Drinking Water Regulation (NPDWR) for the contaminant. A decision not to regulate a contaminant is considered a final Agency action and is subject to judicial review. The Agency can choose to publish a Health Advisory (a nonregulatory action) or other guidance for any contaminant on the CCL that does not meet the criteria for regulation.

The available toxicological data indicate that naphthalene has the potential to cause adverse health effects in humans and animals at high doses. In humans, hemolytic anemia is the most common manifestation of naphthalene toxicity. There are inadequate data to support a conclusion about the carcinogenicity of naphthalene by the oral route of exposure.

Monitoring data indicate that naphthalene is infrequently detected in public water supplies. When naphthalene is detected, it very rarely exceeds the Health Reference Level (HRL) or a value of one-half of the HRL. The available data for naphthalene production show downward trends. The physiochemical properties of naphthalene, and the available data for environmental fate, indicate that naphthalene in surface water is likely to be rapidly degraded by biotic and abiotic processes and that it has little potential for bioaccumulation. Based on these data, it is unlikely that naphthalene will occur in public water systems at frequencies or concentration levels that are of public health concern.

EPA considers exposure to both the general public and sensitive populations, including the fetus, infants, and children, in making its regulatory determination. Approximately 6 to 10 million people are served by PWSs with detections greater than the Minimum Reporting Level. Based on Round 1 monitoring, an estimated 16,000 individuals (about 0.007% of the population served by PWSs) are exposed to naphthalene at levels that exceed both one-half the HRL and the HRL. However, this estimate was heavily influenced by results from samples collected at two ground water systems in one of the cross-section States that can be considered to be outlier values. The Round 2-based estimate of 5,000 individuals (approximately 0.002% of the population served) exposed to concentrations greater than ½ the HRL with no exposures at concentrations greater than the HRL appears to be a better estimate of possible national exposure.

Infants and neonates (approximately 1.3% of the national population) and the fetus (approximately 2.4% of the national population) may experience greater sensitivity to naphthalene toxicity than the general population. Individuals deficient in the G6PD enzyme (approximately 5.2%-11.5% of the national population) are also believed to be more sensitive to development of hemolytic anemia than the general population. When average daily intakes from drinking water are compared with intakes from food, air and soil, drinking water accounts for a relatively small proportion of total naphthalene intake. These observations suggest that naphthalene regulation in drinking water would not present a meaningful opportunity for health risk reduction.

While there is evidence that naphthalene may have adverse health effects in humans at high doses, it is unlikely that it will occur in drinking water at frequencies or concentrations that are of public health concern or that regulation of naphthalene represents a meaningful opportunity for health risk reduction in persons served by public water systems. Preliminary CCL regulatory determinations and further analysis will be presented in the *Federal Register* Notice.

References

- Agency for Toxic Substances and Disease Registry (ATSDR). 1995. *Toxicological Profile for Naphthalene (Update)*. Atlanta: Agency for Toxic Substances and Disease Registry. 200pp.
- ATSDR. 1996. *ToxFAQ for Naphthalene*. Atlanta: Agency for Toxic Substances and Disease Registry. Available on the Internet at <http://www.atsdr.cdc.gov/toxfaq.html> Last modified June 21, 2001.
- ATSDR. 2000. *Hazardous Substance Release and Health Effects Database*. Available on the Internet at: <http://www.atsdr.cdc.gov/hazdat.htm> Last modified August 19, 2000.
- Batelle Columbus Laboratories (BCL). 1980a. Unpublished subchronic toxicity study: naphthalene (C52904) Fisher 344 rats. Report to the US Department of Health and Human Services, National Toxicology Program, Research Triangle Park, NC, by BCL, Columbus, OH, under Subcontract No. 76-34-106002.
- BCL. 1980b. Unpublished subchronic toxicity study: naphthalene (C52904) B6C3F₁ mice. Report to the US Department of Health and Human Services, National Toxicology Program, Research Triangle Park, NC, by BCL, Columbus, OH, under Subcontract No. 76-34-106002.
- Cadmus Group, Inc (Cadmus). 2000. *Methods for Estimating Contaminant Occurrence and Exposure in Public Drinking Water Systems in Support of CCL Determinations*. Draft report to USEPA, Washington, D.C., by Cadmus Group, Waltham, MA, July 25, 2000.
- Cadmus. 2001. *Occurrence estimation methodology and occurrence findings report for six-year regulatory review*. Draft report to USEPA, Washington, D.C., by Cadmus Group, Waltham, MA, October 5, 2001.
- Gidron, E. and J. Leurer. 1956. Naphthalene poisoning. *Lancet*. 4:228-230 (as cited in ATSDR, 1995).
- Gilliom, R.J., D.K. Mueller, and L.H. Nowell. 1998. *Methods for comparing water-quality conditions among National Water-Quality Assessment Study Units, 1992-95*. US Geological Survey Open-File Report 97-589. Available on the Internet at: <http://ca.water.usgs.gov/pnsp/rep/ofr97589/> Last updated October 09, 1998.
- Holmen, J.B., B. Ekesten and B. Lundgren. 1999. Naphthalene-induced cataract model in rats: A comparative study between slit and retroillumination images, biochemical changes and naphthalene dose and duration. *Curr. Eye Res.* 19(5):418-425.
- Howard, P.H. 1989. *Handbook of environmental fate and exposure data for organic chemicals: Volume 1: Large production and priority pollutants*. Chelsea, MI: Lewis Publishers, Inc. 574 pp.
- Kolpin, D.W., J.E. Barbash, and R.J. Gilliom. 2000. Pesticides in ground water of the United States, 1992-1996. *Ground Water*. 38(6):858-863.
- Lapham, W.W., K.M. Neitzert, M.J. Moran, and J.S. Zogorski. 1997. USGS compiles data set for national assessment of VOCs in ground water. *G. Water Mon. Rem.* 17(4):147-157.
- Larson, S.J., R.J. Gilliom, and P.D. Capel. 1999. *Pesticides in streams of the United States--Initial results from the National Water-Quality Assessment Program*. US Geological Survey

- Water-Resources Investigations Report 98-4222. 99 pp. Available on the Internet at: <http://water.wr.usgs.gov/pnsp/rep/wrir984222/> Last modified May 6, 1999.
- Leahy, P.P., and T.H. Thompson. 1994. *The National Water-Quality Assessment Program*. US Geological Survey Open-File Report 94-70. 4 pp. Available on the Internet at: <http://water.usgs.gov/nawqa/NAWQA.OFR94-70.html> Last modified August 23, 2000.
- Lezenius, A. 1902. [A case of naphthalene cataract in man]. *Monatblätter für Augenheilkunde*. 40:129-141 (original in German; as cited in USEPA, 1998c).
- Lopes, T.J. and S.G. Dionne. 1998. *A Review of semivolatile and volatile organic compounds in highway runoff and urban stormwater*. US Geological Survey Open-File Report 98-409. 67 pp.
- Luzzatto, L. and A. Mehta. 1989. Glucose-6-phosphate dehydrogenase deficiency. In: *The Metabolic basis of inherited disease*. Ed. C. Scriver, A.L. Beaudet, W.S. Sly, and D. Valle. New York: McGraw Hill Information Services Co. pp. 2237-2239.
- Miller, T. 2000. *Selected findings and current perspectives on urban water quality--the National Water Quality Assessment (NAWQA) program of the US Geological Survey*. Paper presented to the NAWQA National Liaison Committee, June 13, 2000. 8 pp.
- National Toxicology Program (NTP). 1991. Final developmental toxicity of naphthalene (CAS no. 91-20-3) in Sprague-Dawley CD rats on gestational day 6–15. Report to NTP by Research Triangle Institute, Research Triangle Park, NC, under Contract No. NO1-ES-95255 (as cited in USEPA, 1998c).
- NTP. 1992. *Toxicology and carcinogenesis studies of naphthalene (CAS no. 91-20-3) in B6C3F₁ mice (inhalation studies)*. NTP Technical report series No. 410. NIH Publication No. 92-3141.
- Shopp, G.M., K.L. White, Jr., M.P. Holsapple, et al. 1984. Naphthalene toxicity in CD-1 mice: general toxicology and immunotoxicology. *Fund. Appl. Toxicol.* 4:406-419.
- Speth, T.F. and J.Q. Adams. 1993. GAC and air-stripping design support for the Safe Drinking Water Act. In: *Strategies and technologies for meeting SDWA requirements*. Eds. R. Clark and R.S. Summers. Lancaster, PA: Technomic Publ. Co.
- Squillace, P.J., M.J. Moran, W.W. Lapham, C.V. Price, R.M. Clawges, and J.S. Zogorski. 1999. Volatile organic compounds in untreated ambient groundwater of the United States, 1985-1995. *Env. Sci. and Tech.* 33(23):4176-4187.
- U.S. Department of Health and Human Services (USDHHS). 1993. *Registry of toxic effects of chemical substances (RTECS, online database)*. Available on the Internet at: <http://www.epa.gov/ttn/uatw/hlthef/naphthal.html> Last modified May 26, 1998.
- U.S. Environmental Protection Agency (USEPA). 1987. National Primary Drinking Water Regulations-Synthetic Organic Chemicals; Monitoring for Unregulated Contaminants; Final Rule. *Federal Register* 52, no. 130 (8 July): 25690.
- USEPA. 1990. *Drinking water health advisory for naphthalene*. Washington, D.C. : Office of Assistant Administrator for Water. 28 pp.

- USEPA. 1991. National Primary Drinking Water Regulations - Synthetic Organic Chemicals and inorganic Chemicals; Monitoring for Unregulated Contaminants; National Primary Drinking Water Regulations Implementation; National Secondary Drinking Water Regulations; Final Rule. *Federal Register* 56, no. 20 (30 January): 3526.
- USEPA. 1992. Drinking Water; National Primary Drinking Water Regulations – Synthetic Organic Chemicals and Inorganic Chemicals; National Primary Drinking Water Regulations Implementation. *Federal Register* 57, no. 138 (17 July): 31776.
- USEPA. 1996a. *Emergency planning and community right-to-know section 313, list of toxic chemicals*. 45 pp. Available on the Internet at: <http://www.epa.gov/tri/chemls2.pdf> Last modified March 23, 2000. Link to site at: <http://www.epa.gov/tri/chemical.htm>
- USEPA. 1996b. *Drinking Water Regulations and Health Advisories*. Office of Water. EPA Report 822-B-96-002. 16 pp.
- USEPA. 1998a. *Laws & Regulations*. Washington, DC: Environmental Protection Agency. Available on the Internet at: <http://www.epa.gov/reg5foia/pest/history.html> Last modified August 20, 1998.
- USEPA. 1998b. Announcement of the Drinking Water Contaminant Candidate List; Notice. *Federal Register* 63, no. 40 (2 March): 10273.
- USEPA. 1998c. *Toxicological Review of Naphthalene (CAS 91-20-3): In support of summary information on the Integrated Risk Information System (IRIS)*. Washington, D.C.: USEPA. 124 pp. Available on the Internet at: <http://www.epa.gov/iris/toxreviews/nap-tox2.pdf> Link to site at: <http://www.epa.gov/iris/subst/0436.htm>
- USEPA. 1999a. Suspension of Unregulated Contaminant Monitoring Requirements for Small Public Water Systems; Final Rule and Proposed Rule. *Federal Register* 64, no. 5 (8 January): 1494.
- USEPA. 1999b. Revisions to the Unregulated Contaminant Monitoring Regulation for Public Water Systems; Final Rule. *Federal Register* 64, no. 180 (17 September): 50556.
- USEPA. 1999c. *Superfund hazardous waste site basic query form*. Washington, D.C.: USEPA. Available on the Internet at: <http://www.epa.gov/superfund/sites/query/basic.htm> Last modified December 1, 1999.
- USEPA. 1999d. *A Review of Contaminant Occurrence in Public Water Systems*. Office of Water. EPA Report 816-R-99-006. 78 pp.
- USEPA. 2000a. *Regulatory Matrix of TRI Chemicals in other Federal Programs*. Washington, D.C.: USEPA. Available on the Internet at: www.epa.gov/tri/chemicals.htm Last modified March 23, 2000.
- USEPA. 2000b. *TRI Explorer: Are year-to-year changes comparable?* Washington, D.C.: USEPA. Available on the Internet at: www.epa.gov/triexplorer/yearsum.htm Last modified May 5, 2000.
- USEPA. 2000c. *TRI Explorer: Trends*. Washington, D.C.: USEPA. Available on the Internet at: <http://www.epa.gov/triexplorer/trends.htm> Last modified May 5, 2000.

- USEPA. 2000d. *The Toxic Release Inventory (TRI) and Factors to Consider when Using TRI Data*. Washington, D.C.: USEPA. Available on the Internet at: <http://www.epa.gov/tri/tri98/98over.pdf> Last modified August 11, 2000. Link to site at: <http://www.epa.gov/tri/tri98>
- USEPA. 2000e. *What is the Toxic Release Inventory?* Washington, D.C.: USEPA. Available on the Internet at: <http://www.epa.gov/tri/general.htm> Last modified February 28, 2000.
- USEPA. 2000f. *Drinking Water Standards and Health Advisories*. Office of Water. EPA Report 822-B-00-001.
- USEPA. 2000g. *Water industry baseline handbook*. Second Edition (Draft). Washington, D.C.: US Environmental Protection Agency.
- USEPA. 2001a. *Analysis of national occurrence of the 1998 Contaminant Candidate List regulatory determination priority contaminants in public water systems*. Office of Water. EPA report 815-D-01-002. 77 pp and appendices.
- USEPA. 2001b. *Health effects support document for Naphthalene*. External review draft. Office of Water. EPA report 815-R-01-017. 150 pp.
- USEPA. 2001c. *Occurrence of unregulated contaminants in public water systems: An initial assessment*. Office of Water. EPA report 815-P-00-001. 50 pp.

Appendix A: Abbreviations and Acronyms

ACGIH	- American Conference of Governmental Industrial Hygienists
ATSDR	- Agency for Toxic Substances and Disease Registry
CAS	- Chemical Abstract Service
CCL	- Contaminant Candidate List
CERCLA	- Comprehensive Environmental Response, Compensation & Liability Act
CMR	- Chemical Monitoring Reform
CWS	- community water system
ECD	- electron capture detectors
ELCD	- electrolytic conductivity detector
EPA	- Environmental Protection Agency
EPCRA	- Emergency Planning and Community Right-to-Know Act
FDA	- Food and Drug Administration
FIFRA	- Federal Insecticide, Fungicide, and Rodenticide Act
FQPA	- Food Quality Protection Act
FR	- federal register
G6PD	- glucose-6-phosphate dehydrogenase
GAC	- granular activated carbon (treatment technology for organic compounds)
GC	- gas chromatography (a laboratory method)
g/mol	- grams per mole
GW	- ground water
HAL	- Health Advisory level
HazDat	- Hazardous Substance Release and Health Effects Database
HRL	- Health Reference Level
IOC	- inorganic compound
IRIS	- Integrated Risk Information System
K _{oc}	- organic carbon partition coefficient
K _{ow}	- octanol-water partitioning coefficient
L	- liter
LOAEL	- lowest observed adverse effect level
MCL	- maximum contaminant level
MCLG	- maximum contaminant level goal
MDL	- method detection limit
mg	- milligram
mg/kg-day	- milligram per kilogram per day
mm Hg	- millimeter mercury
MRL	- minimum reporting level
MS	- mass spectrometry (a laboratory method)
MSHA	- Mine Safety and Health Administration
NAWQA	- National Water Quality Assessment Program
NCOD	- National Drinking Water Contaminant Occurrence Database
NDWAC	- National Drinking Water Advisory Council
NIOSH	- National Institute for Occupational Safety and Health
NIRS	- National Inorganic and Radionuclide Survey
nm	- nanometer
NOAEL	- no observed adverse effect level
NPDES	- National Pollution Discharge Elimination System
NPDWR	- National Primary Drinking Water Regulation
NPL	- National Priorities List

NPS	- National Pesticide Survey
NTNCWS	- non-transient non-community water system
NTP	- National Toxicology Program
NURP	- National Urban Runoff Program
OGWDW	- Office of Ground Water and Drinking Water
ORD	- Office of Research and Development
OSHA	- Occupational Safety and Health Administration
PID	- photoionization detector
ppm	- part per million
PWS	- public water system
RCRA	- Resource Conservation and Recovery Act
RfD	- reference dose
SARA Title III	- Superfund Amendments and Reauthorization Act
SDWA	- Safe Drinking Water Act
SDWIS/FED	- Federal Safe Drinking Water Information System
SOC	- synthetic organic compound
SW	- surface water
TRI	- Toxic Release Inventory
UCM	- Unregulated Contaminant Monitoring
UCMR	- Unregulated Contaminant Monitoring Regulation/Rule
URCIS	- Unregulated Contaminant Monitoring Information System
USDHHS	- United States Department of Health and Human Services
USEPA	- United States Environmental Protection Agency
USGS	- United States Geological Survey
VOC	- volatile organic compound
µg	- micrograms
>MCL	- percentage of systems with exceedances
>MRL	- percentage of systems with detections